MEDICAL CARE QUALITY RESEARCH AND IMPROVEMENT ACT OF 1989

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

H.R. 1692

TO AMEND TITLE XI OF THE SOCIAL SECURITY ACT TO PROVIDE FUNDING FOR RESEARCH AND EDUCATION INTO THE OUTCOME, EFFECTIVENESS, AND APPROPRIATENESS OF MEDICAL TREATMENTS UNDER THE MEDICARE AND OTHER PROGRAMS

MAY 24, 1989

Serial 101-47

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PRINTING OFFICE

21-788 WASHINGTON : 1989

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Public Laws: 101st Congress / 1st Session / House
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MEDICAL CARE QUALITY RESEARCH AND IMPROVEMENT ACT OF 1989

WEDNESDAY, MAY 24, 1989

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The committee met, pursuant to notice, at 9:07 a.m., in room 1100, Longworth House Office Building, Hon. Fortney Pete Stark (chairman of the subcommittee) presiding.

[The press releases announcing the hearing follow:]

FOR IMMEDIATE RELEASE
THURSDAY, MAY 11, 1989

PRESS RELEASE #15
SUBCOMMITTEE ON HEALTH
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515
TELEPHONE: (202) 225-7785

THE HONORABLE FORTNEY PETE STARK (D., CALIF.), CHAIRMAN,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES,
ANNOUNCES A HEARING ON
H.R. 1692, THE MEDICAL CARE QUALITY RESEARCH AND
IMPROVEMENT ACT OF 1989

The Honorable Fortney Pete Stark (D., Calif.), Chairman, Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, today announced that the Subcommittee will hold a hearing on H.R. 1692, The Medical Care Quality Research and Improvement Act of 1989. The hearing will be held on Wednesday, May 24, 1989, beginning at 10:00 a.m., in the main Committee hearing room, 1100 Longworth House Office Building.

In announcing the hearing, Chairman Stark said: "There are wide variations in how medicine is practiced, with inevitable effects on both the cost and quality of care. This hearing will explore the reasons for these variations, and hopefully will address steps that could be taken to improve the overall quality of medical care."

Oral testimony will be heard from invited witnesses only. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND

Research has demonstrated wide variations in patterns of medical practice, such as:

* Residents of New Haven are twice as likely to undergo coronary artery bypass surgery as residents of Boston;

* In one community in Maine, nearly 70 percent of women have had a hysterectomy by age 70, while the rate is only 20 percent in another community;

* In Vermont, only eight percent of children in one community had a tonsillectomy, while nearly 70 percent of children in another community had tonsillectomies.

Researchers have not been able to explain these variations by differences between populations living in these communities. Rather, the variations appear to be related to a lack of uniformity in medical practice.

Other research has explored the appropriateness of medical procedures. This research has shown that a significant number of procedures are performed for inappropriate reasons:

* In a study of Medicare patients, only 56 percent of coronary artery bypass operations were performed for clearly appropriate reasons (14 percent were performed for inappropriate reasons, while the appropriateness of the remainder was equivocal).

* Another study found that up to 20 percent of all pacemaker implantations may be inappropriate.

H.R. 1692 was introduced on April 5, 1989, by The Honorable Bill Gradison (R., Ohio), Ranking Minority Member of the Subcommittee, and Chairman Stark. This bill would initiate a national effort of research on the outcomes, effectiveness, and appropriateness of medical treatments. Information developed would then be disseminated to providers and physicians, and used to develop practice guidelines.

The President's budget for fiscal year 1990 includes $52 million to fund such research. The Physician Payment Review Commission, as well as various physician organizations, have also endorsed such efforts.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

For those who wish to file a written statement for the printed record of the hearing, six (6) copies are required and must be submitted by the close of business on Friday, June 9, 1989, to Robert J. Leonard, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. An additional supply of statements may be furnished for distribution to the press and public if supplied to the office of the Subcommittee on Health, 1114 Longworth House Office Building, before the hearing begins.

SEE FORMATTING REQUIREMENTS BELOW:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will **not** be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages.
2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.
3. Statements must contain the name and capacity in which the witness will appear or, for written comments, the name and capacity of the person submitting the statement, as well as any clients or persons, or any organization for whom the witness appears or for whom the statement is submitted.
4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and public during the course of a public hearing, may be submitted in other forms.

* * * * *

* * * CHANGE OF TIME * * *

FOR IMMEDIATE RELEASE
WEDNESDAY, MAY 17, 1989

PRESS RELEASE #15-REVISED
SUBCOMMITTEE ON HEALTH
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515
TELEPHONE: (202) 225-7785

THE HONORABLE FORTNEY PETE STARK (D., CALIF.), CHAIRMAN,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES
ANNOUNCES A NEW TIME FOR THE HEARING ON
H.R. 1692, THE MEDICAL CARE QUALITY RESEARCH AND
IMPROVEMENT ACT OF 1989

The Honorable Fortney Pete Stark (D., Calif.), Chairman, Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, today announced that the Subcommittee's hearing on H.R. 1692, the Medical Care Quality Research and Improvement Act of 1989, originally scheduled for 10:00 a.m., Wednesday, May 24, 1989, has been rescheduled for 9:00 a.m., in the main Committee hearing room, 1100 Longworth House Office Building.

All other details for the hearing remain the same. (See press release #15, dated May 11, 1989.)

* * * * *

101ST CONGRESS
1ST SESSION

H. R. 1692

To amend title XI of the Social Security Act to provide funding for research and education into the outcome, effectiveness, and appropriateness of medical treatments under the Medicare and other programs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 5, 1989

Mr. GRADISON (for himself and Mr. STARK) introduced the following bill; which was referred jointly to the Committees on Ways and Means and Energy and Commerce

---

A BILL

To amend title XI of the Social Security Act to provide funding for research and education into the outcome, effectiveness, and appropriateness of medical treatments under the Medicare and other programs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Care Quality Research and Improvement Act of 1989".

SEC. 2. PURPOSE.

The purpose of this Act is to create a research and education program which can assist the medical community in

promoting the use of the most appropriate and cost-effective medical treatment for conditions where knowledge is available or can be developed to improve such treatment.

SEC. 3. RESEARCH AND EDUCATION CONCERNING THE OUTCOME, EFFECTIVENESS, AND APPROPRIATENESS OF MEDICAL TREATMENT.

Title XI of the Social Security Act is amended by inserting after section 1139 the following new section:

"RESEARCH AND EDUCATION CONCERNING THE OUTCOME, EFFECTIVENESS, AND APPROPRIATENESS OF MEDICAL TREATMENT

"SEC. 1140. (a) RESEARCH.—The Secretary shall provide for outcome, effectiveness, and appropriateness research (as defined in subsection (h)) with respect to specific medical treatment or specific medical conditions (selected under subsection (f)(2)(C)). Such research shall include the following:

"(1) Review of existing research findings with respect to such treatment or conditions.

"(2) Review of the existing methodologies that use large data bases in conducting such research and development of new research methodologies with respect to such research.

"(3) Grants and contracts to research centers, and contracts to other entities, to conduct such research on such treatment or conditions.

"(4) Development of projects, using a variety of entities producing, processing, or reviewing claims for medical treatment, to demonstrate the use of claims information and information on clinical and functional status of patients in determining the outcome, effectiveness, and appropriateness of such treatment.

"(b) STANDARDS FOR RESEARCH INFORMATION.—In order to promote the research described in subsection (a) through the use of a wider base of information which can be linked together, the Secretary shall develop standards to be used in the collection and maintenance of information (whether by the Secretary or others) which may be used in such research and, to the extent necessary, may supplement information collected to perform such research. In developing such standards, the Secretary shall develop—

"(1) uniform definitions of information to be collected and used in describing a patient's clinical and functional status;

"(2) common reporting formats for such information; and

"(3) standards to assure the security, accuracy, and appropriate maintenance of such information.

Not later than 1 year after the date of the enactment of this section, the Secretary shall report to Congress on the feasibility of linking such research-related information of the De-

partment with such information collected or maintained by other Federal departments (including the Departments of Defense and Veterans' Affairs and the Office of Personnel Management) and by other organizations.

"(c) DISSEMINATION OF FINDINGS AND EDUCATION OF PROVIDERS.—The Secretary shall provide for the dissemination of the findings of research described in subsection (a) and for the education of providers in the application of such research. In disseminating such findings and providing for such education, the Secretary shall develop—

"(1) a program designed to educate physicians and other providers with respect to such findings, including a formal training program for training physician managers within provider organizations; and

"(2) appropriate relationships between the Department and professional medical associations and societies.

"(d) DEVELOPMENT OF GUIDELINES.—(1) The Secretary shall develop—

"(A) treatment-specific or condition-specific practice guidelines, based on research described in subsection (a), and

"(B) for each such guideline, models through which—

" (i) physicians and other providers may use such guideline, and

"(ii) other entities may use such guideline in reviewing quality and appropriateness of medical care.

"(2) The Secretary shall initiate, by not later than January 1, 1991, a project to apply the guidelines developed under paragraph (1)(A) to at least 3 clinical treatments or conditions (selected under subsection (f)(2)(C)) that (A) account for a significant portion of expenditures under title XVIII and (B) have a significant variation in the frequency or the type of treatment provided.

"(e) ADVISORY COUNCIL.—(1) The Secretary shall provide a charter for, and appointment of 18 members to, an advisory council to assist the Secretary in activities conducted under this section.

"(2) The membership on the advisory council shall consist of representatives from a broad range of interested parties, including professional provider associations and societies, provider education associations, health policy research associations, health care insurers, employer groups, provider accreditation groups, hospital associations, health care consumers, and the Departments of Defense and Veterans' Affairs.

"(3) The advisory council shall comment and advice the Secretary regarding each annual coordination plan transmitted by the coordinating group under subsection (f)(2)(A).

"(4) The Assistant Secretary for Health is responsible for providing the advisory council with such staff and technical assistance as may be required.

"(5) Section 14 of the Federal Advisory Committee Act shall not apply to the advisory council.

"(f) COORDINATING GROUP.—(1) The Secretary shall establish a coordinating group composed of the Assistant Secretary for Health, the Assistant Secretary for Planning and Evaluation, and the Administrator of the Health Care Financing Administration. The Assistant Secretary for Health shall serve as chairman of the coordinating group.

"(2) The coordinating group shall—

"(A) annually transmit to the Secretary a plan to coordinate the activities of the Department in the activities described in this section,

"(B) annually establish an agenda (including priorities) for activities under this section and periodically monitor and review activities conducted under this section (including coordination and information exchange), and

"(C) select—

"(i) the specific treatments and medical conditions to be the subject of research under subsection (a), and

"(ii) the treatments and medical conditions to be the subject of guidelines under subsection (d)(2), of which at least two-thirds must have the concurrence of the Administrator of the Health Care Financing Administration.

"(g) AUTHORIZATION OF APPROPRIATIONS.—(1) There are authorized to be appropriated to carry out this section—

"(A) $72,000,000 for fiscal year 1990,

"(B) $110,000,000 for fiscal year 1991,

"(C) $170,000,000 for fiscal year 1992,

"(D) $225,000,000 for fiscal year 1993, and

"(E) $270,000,000 for fiscal year 1994.

"(2) Two-thirds of the amounts authorized to be appropriated under paragraph (1) for any fiscal year are hereby transferred to carry out this section in the following proportions from the following trust funds:

"(A) 60 percent from the Federal Hospital Insurance Trust Fund (established under section 1817).

"(B) 40 percent from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

"(3) Of the amounts transferred or otherwise appropriated to carry out this section in fiscal year 1990—

"(A) ⅓ shall be allotted for the activities described in subsection (a),

"(B) ⅓ shall be allotted for the activities described in subsection (b),

"(C) ⅙ shall be allotted for activities described in subsection (c), and

"(D) ⅙ shall be allotted for activities described in subsection (d).

"(h) DEFINITIONS.—In this section:

"(1) The term 'outcomes research' means, with respect to a medical condition, research that—

"(A) focuses on the evaluation of a treatment or alternative treatments for the condition, and

"(B) formally assesses the probabilities for the full spectrum of different outcomes and the value of these outcomes for patients, including mortality, morbidity, functional status, symptoms, and quality of life.

"(2) The term 'effectiveness research' means, with respect to a treatment, research that focuses on—

"(A) the uses of the treatment for patients in typical clinical practice and the impact on outcome of the treatment of those patients, taking

into account (to the extent relevant) patient conditions and local environment, and

"(B) through routine monitoring and feedback of information to physicians and patients, on changes in the treatment to improve outcomes in such practice.

"(3) The term 'appropriateness research' means, with respect to a treatment, an assessment, which may be based on outcomes research, effectiveness research, or a consensus of medical experts or expert judgment, of the characteristics of particular patients for which the treatment is effective.".

○

Chairman STARK. Good morning, the Subcommittee on Health of the Ways and Means Committee is meeting today to consider H.R. 1692, the Medical Care Quality Research and Improvement Act of 1989.

It was introduced by my colleague, Mr. Gradison, and myself on April 5, and provides support for research and outcomes effectiveness and appropriateness of medical treatment. S. 702, a similar bill, was introduced by Senator Mitchell.

Research has shown there is a substantial uncertainty in the outcomes of many medical treatments. Often there is disagreement over the most appropriate treatment. This uncertainty is demonstrated by wide variations in the use of treatments between geographic areas.

For instance, residents in New Haven are twice as likely to undergo coronary artery bypass surgery as residents of Boston. In Vermont, only 8 percent of children in one community had their tonsils out while nearly 70 percent in another community had tonsillectomies.

These variations cannot be explained by differences in the populations of these communities or by differences in access to care.

One study of dozens of articles on the treatment of glaucoma found virtually no usable evidence about the effectiveness of medical treatment for this common condition. Reviews of studies of treatments for other conditions have arrived at similar conclusions.

H.R. 1692 responds to concerns by providing financial support for medical outcomes and effectiveness research ensuring that the research findings become widely available through development of educational programs for physicians and other providers, and support development of guidelines that could be used by physicians in their own practices.

I would like to thank Mr. Gradison for taking the lead in the development of this bill. I am pleased that the administration has shown interest in the outcome and effectiveness research demonstrated by the presence of Dr. Sullivan, Secretary of Health and Human Services at today's hearing.

I hope the administration will join the Congress in support of these efforts as we proceed through our budget reconciliation process in the coming weeks.

Mr. Gradison.

Mr. GRADISON. Thank you, Mr. Chairman. Thank you, in particular, for calling a hearing on this subject in such a timely basis so that we can consider whether to include a bill on these lines or along the lines of Senator Mitchell's proposal in our reconciliation package.

What we are talking about today is not a new idea. The administration has been doing some work on a limited basis along these lines in recent years, and so has the medical profession. In a sense, what we are trying to do is to build upon the experience which is already out there and to try to accelerate research into the appropriate way of treating certain very common medical problems.

One of the things that has struck me as a layman is that we are spending about $4 billion a year in the public and private sectors to assure the safety and adequacy of drugs, but we have relatively little work going on in comparison with regard to the safety of spe-

cific medical procedures, or in some instances whether the appropriate treatment is a medical procedure such as surgery or the use of some of the newer drugs which are becoming available.

I very much hope and expect that out of this hearing we will have enough information to be able to make a balanced judgment as to the next steps.

Thank you, Mr. Chairman.

Chairman STARK. Thank you.

Our first witness this morning is the distinguished Dr. Louis Sullivan, Secretary of the Department of Health and Human Services. Doctor, you honor us with your presence here today, and it is testimony to the importance that you attach to the development of an improved basis for medical decisions.

The subcommittee looks forward to working with you on this and other issues. Welcome to the subcommittee, and without objection any prepared material you care to leave with us will be in the record in its entirety, and you may proceed to enlighten us. Expand on your testimony in any way you are comfortable.

STATEMENT OF HON. LOUIS W. SULLIVAN, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JAMES MASON, M.D., ASSISTANT SECRETARY FOR HEALTH, AND LOUIS HAYES, ACTING ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Secretary SULLIVAN. Thank you very much, Mr. Chairman. I am joined this morning by Dr. James Mason, on my right, our Assistant Secretary for Health, and by Mr. Louis Hayes, on my left, our Acting Administrator for the Health Care Financing Administration, two members of our Department who are intimately involved and will continue to be involved in addressing the issues of effectiveness research.

It is indeed a pleasure to be here before you, Mr. Gradison, Representative Johnson, Representative Coyne, and Representative Moody, and other members of the subcommittee, to address the issue of effectiveness research in medical treatment.

I am especially pleased to note that we share the same objectives with respect to this important initiative as evidenced by the legislation which is the subject of this hearing.

I would like to begin by describing the rationale for our approach to the research and by providing a brief description of the medical treatment effectiveness initiative that we have proposed for fiscal year 1990.

The initiative has as its central goals: First, improving the quality of health care received by Americans; second, reducing ineffective and unnecessary medical treatments and comparing the cost effectiveness of alternative treatment modalities; third, enhancing the scientific basis of medicine through development and application of technology to the issues of medical treatment effectiveness; and fourth, providing information to patients, physicians, and others on appropriateness, risk, and benefits of medical interventions.

Our initiative has three major components to reach these goals. One, significant expansion of our research on patient outcomes and

clinical effectiveness; two, expansion and enhancement of our current clinical and claims data for Medicare patients and improvement in ability to link those data with information on those under age 65 years of age; and three, dissemination of the findings of our research and data analysis to the medical community and to the public.

The initiative will rely heavily on cooperative, complementary, and coordinated activities making use of the unique strengths and capabilities of a number of components within our Department, in partnership with the medical community and others in the private sector.

The term initiative in this case perhaps understates the long commitment of the Department, as noted by Mr. Gradison, both to performing research in patient outcomes and to ensuring high quality medical practice.

Health and Human Services has supported medical treatment effectiveness research for almost two decades. The evolution of this research endeavor is worth recounting briefly. It is, in many ways, a model of scientific inquiry.

Initial studies funded by the Department, known as small area variations research, demonstrated that differences in usage rates for surgical and medical procedures in different communities existed even when researchers had adjusted results for variations in the composition of the population or local environmental hazards. In many cases, the findings were quite dramatic.

Questions raised by these early studies naturally led researchers to a second stage of inquiry, namely patient outcomes research. This research examined patient morbidity, mortality, and quality of life using data bases such as our Medicare files. Patient outcomes research has the potential to allow assessment of the long-term risks and benefits of various medical procedures and treatments.

Significant findings from this early work coupled with the concern about rising health care costs led Congress to include language in the Omnibus Budget Reconciliation Act of 1986 which directed my Department to establish a patient outcome assessment research program. This authority resulted in an expansion of previous efforts.

In carrying out the overt 1986 directive, HHS has given priority to treatments and procedures for which the intervention poses a high risk or offers a high potential benefit to the patient. Data indicate a highly variable pattern of provider practices within a distinct geographic area and among different geographic areas, and the intervention is significant in terms of utilization, length of hospital stay, or cost.

Thus far, our studies have focused on procedures utilized by Medicare beneficiaries and have included research in such areas as heart disease, hypertension, diabetes, rheumatoid arthritis, and prostatectomy.

This year we will spend approximately $6 million to support both investigator-initiated research and multidisciplinary studies of significant or controversial medical treatment effectiveness issues.

Because of growing success in effectiveness research, the Department was convinced that ultimately research findings would lead

to the development of patient outcome information necessary for decisionmaking that will improve medical care.

Our fiscal year 1990 initiative is a significant step forward in our effort to define, measure, and assure the quality of medical care. Its focus is identification of treatments or therapeutic procedures that produce the best patient outcomes as well as dissemination of that information to the practicing community.

This initiative will permit us to use our previous experiences and to begin building a system that over the long term reduces and may even eliminate inappropriate health care while controlling costs. This is an area of research in which patients, physicians, and payers have a vital stake.

In addition to an expanded patient outcomes research effort, the medical effectiveness initiative includes essential data-related activities. Enhanced Medicare information will be accessible to researchers. Existing data files will be linked and additional data sources will be tapped.

As our research is completed, the results will be disseminated widely both to the health care practice community who can employ this information to make better informed decisions of outpatient care and to patients themselves who want to make educated decisions about their own health care.

Consultation with the outside community, including health care consumers, will continue to be very important to the success of this initiative. We recognize that cooperation with the medical community and with academic institutions which train health care providers is essential. The best way to achieve collaboration is to involve in each stage of the process those who will later be using the information.

With this in mind, we have involved a variety of individuals and organizations in discussions of our initiative, and we are working also with the National Academy of Sciences to help define priorities for the effectiveness research agenda through the Institute of Medicine.

In addition, we are proceeding to establish a medical effectiveness advisory council which will provide a link between the Department and the outside community, and will provide assistance in setting directions for our programs and help us to ensure the highest quality research possible.

I would now like to turn to a discussion of H.R. 1692. I am struck by the fact that the underlying principles of this bill reflect many of the principles envisioned by the administration's proposal. This includes the importance of medical care treatment effectiveness research, data development, and information dissemination, as well as a flexible approach to managing activities in this area.

In addition to acknowledging the need for flexibility in determining roles to be played in the initiative by the various components of the Department, you recognize in your bill that two of the key requirements for success are careful coordination within the Department and involvement of the medical community in an advisory capacity. You also appear to share our view that a very high premium must be placed on disseminating our research results and educating health care providers.

Finally, the bill illustrates that you recognize as we did in developing the fiscal year 1990 budget that to accomplish the critical objectives of such a program and to have a meaningful impact on health care would require a significant increase over previous funding levels.

Let me be a bit more specific about some of the provisions of H.R. 1692. Section 3 of the bill authorizes a program of research very similar to what we had proposed in our fiscal year 1990 budget. I believe that it appropriately omits specification of where within the Department the described activities should be carried out.

As each month passes in my tenure, I find new reasons to be impressed by the unique and versatile resources and abilities of the components of our Department, and I want to be able to employ those resources to the best advantage of the Department and its constituents. H.R. 1692 would allow me that flexibility.

Several provisions of the bill deal with mechanisms and policies related to data collection. While I agree that common formats and uniform definitions for the collection and maintenance of information are generally beneficial, I am concerned about an inflexible requirement to apply the same rigid standards to all data systems.

It is possible, it seems to me, to envision cases which might not easily be standardized. I would ask you to discuss this particular issue further with my staff.

Two of my major concerns about H.R. 1692 relate to the bill's requirements for developing medical practice guidelines and to its funding levels and allocation.

I am well aware of the staggering increases in health care costs, and I do not disagree that over the long term a better understanding of the appropriateness and effectiveness of medical treatments should lead to targeting spending for better value of health care. However, I believe we must be careful not to view effectiveness research with its promise of long-term benefits as a short-term panacea for controlling volume or controlling costs.

We are proposing a major expansion of our previous effort because we recognize the need for better information. Time is needed to ascertain the extent to which this information actually will improve medical care and whether and how much this will result in cost reductions. Second, I believe it would take at least several years and possibly considerably longer to connect research findings to medical practice.

With respect to the funding of this initiative, we believe that the funds we have requested in our 1990 budget, a total of $52 million, are sufficient to launch the medical effectiveness initiative. This represents an almost tenfold expansion over current spending, a major increase, especially in light of many other priorities of the Department and the national budget deficit.

Further, your legislation is quite specific about how funds would be allocated to the various components of the initiative. For example, your bill would specify the proportional allocation of funds for research, standards development, education, and information dissemination. Such a formula allocation would hinder flexibility. For example, I am not yet certain what percentage of funds should be

allocated to research versus information dissemination and education.

As there must be a substantial research base from which to launch an education/information effort, we are not yet in a position to begin that aspect of the program. We have just begun to develop the required base of knowledge.

I want to congratulate the subcommittee on its thoughtful, well-considered approach to this issue which has the potential for making a significant contribution to American health care.

I am pleased to have this opportunity to describe our initiative to you, an initiative that is rooted in our recognition of a need for better understanding of what works best in the practice of medicine.

I and my colleagues in the Department look forward to continuing to work with you and the subcommittee as together we seek the goal of effective health care for all of our citizens.

Thank you very much, Mr. Chairman.

[The statement of Secretary Louis W. Sullivan follows:]

STATEMENT BY LOUIS W. SULLIVAN, M.D.
SECRETARY OF HEALTH AND HUMAN SERVICES

Mr. Chairman, it is indeed a pleasure to be here today to discuss medical treatment effectiveness research. I am especially pleased to note that we share similar objectives with respect to this initiative, as evidenced by the legislation that is the subject of this hearing. Your bill indicates to me that you share my view that effectiveness research is essential to an understanding of how we can provide our citizens with the best value in health care. It is clear that President Bush shares our view as well. In his remarks at my swearing-in ceremony on March 10, the President asked that we work to get better value for health care dollars, through targetting effective services and finding ways to contain the escalating costs of medical care -- without compromising the quality of health services.

I would like to begin by describing the rationale for our approach to effectiveness research and providing a brief description of the Medical Treatment Effectiveness Initiative that we have proposed for fiscal year 1990.

This initiative signals a significant step forward in our approach to defining, measuring, and assuring the quality of medical care. Our effectiveness initiative focuses on identifying which treatments or therapeutic procedures produce the best patient outcome and on disseminating that information to the practicing community. This is an area of research in which patients, physicians, and payers have a vital stake. Our leadership in effectiveness research is central to what Dr. Arnold Relman, editor of the New England Journal of Medicine, has called the "Third Revolution" in health care, the era of assessment and accountability.

THE MEDICAL TREATMENT EFFECTIVENESS INITIATIVE

Faced with evidence of enormous variations in practice patterns (often without any apparent medical justification), we determined that it was essential to create a systematic base of information about the quality, effectiveness, and appropriateness of medical procedures and interventions, as well as about demonstrable benefits of interventions to patients.

The initiative has as its central goals:

- Improving the quality of health care received by Americans through the provision of effective, appropriate care, and involving the consensus of the medical community;
- Reducing ineffective and unnecessary medical treatments and comparing the cost-effectiveness of alternative treatment modalities;
- Enhancing the scientific basis of medicine through development and application of technology to the issues of medical treatment effectiveness; and
- Providing information to patients, physicians, and others on appropriateness, risks, and benefits of medical interventions.

The initiative has three major components:

- Significant expansion of our research on patient outcomes and clinical effectiveness;
- Expansion and enhancement of our current clinical and claims data for Medicare patients and improvement in the ability to link those data with information on those under 65 years of age; and
- Dissemination of the findings of our intramural and extramural research and data analysis to the medical community and the public.

The initiative will rely heavily on cooperative, complementary, and coordinated activities, making use of the unique strengths and capabilities of a number of components of the Department, in partnership with the medical community and others in the private sector.

Using our previous work as a foundation, the initiative will build a "library of understanding" about medical practices. This information will then be drawn upon to accomplish the goals I mentioned above. Furthermore, the timing of this initiative is appropriate; technology has progressed so that it is feasible to collect and analyze the information needed to reach useful conclusions.

BACKGROUND

The term "initiative" in this case perhaps understates the long commitment of the Department both to performing patient outcomes research and to ensuring high-quality medical practice. HHS has supported medical treatment effectiveness research for almost two decades. The evolution of this endeavor is worth recounting briefly. It is, in many ways, a model of scientific inquiry.

Initial studies funded by the Department, known as "small area variations" research, demonstrated that differences in usage rates for surgical and medical procedures in different communities existed even when researchers had adjusted results for variations in the composition of the population or local environmental hazards. In many cases, the findings were quite dramatic.

For example, researchers at RAND examined the use in geographical areas of the U.S. of 123 procedures commonly performed on Medicare beneficiaries. For 67 of those procedures, there was at least a threefold difference between the number of such procedures performed in the areas with the highest and lowest utilization rates. With total knee-replacements, the difference was sixfold; for arthroplasty, elevenfold; and for injection of hemorrhoids, an amazing twenty-sixfold difference.

As increasing numbers of studies confirmed such findings, the research raised a series of fundamental questions. Do these rates demonstrate over-utilization or under-utilization? Are there adverse consequences to patients?

Questions raised by these early studies naturally led researchers to a second stage of inquiry, which we call "patient outcomes research." For the purpose of this research, we defined outcome in terms of mortality, morbidity, disability, and quality of life. By drawing on large-scale data bases, such as our Medicare files, researchers were able to begin to look at rates of mortality, rehospitalization, and complications or disability in the months and years following discharge from a hospital. Researchers could include in their studies information not only from these data files, but also from reviews of medical record files. Patient outcomes research has the potential to allow assessment of the long-term benefits and risks of particular procedures, comparison of the risks and benefits of different treatments for the same conditions, and determination of the health implications of over-utilization and under-utilization of specific procedures.

Patient outcomes research was envisioned as a critical complement to both biomedical research and hospital-level case studies because of the long-term implications of specific medical treatments. As a physician and medical educator, I am convinced that the potential contribution of this kind of research to the practice of medicine is enormous.

Two recent examples illustrate the tremendous potential benefit of this type of research. HHS-supported research by Dr. John Wennberg has demonstrated that early prostate surgery does not extend life expectancy and that the risks of prostatectomy are higher than previously suspected. The research results indicate clearly that both physicians and patients need to weigh the benefits and risks of this surgery far more carefully. The long-term implications of such studies become all the more obvious when we realize that prostatectomy is the most frequently employed surgical procedure for male Medicare beneficiaries.

Other work has shed light on a major controversy about "lumpectomy," removal of only the tumor, versus mastectomy, removal of the entire breast, as alternative treatments for breast cancer. Researchers have found that lumpectomy plus radiation is often as effective as a mastectomy for small tumors that have not spread, though there is still some disagreement in the medical community.

CURRENT ACTIVITIES

The promise of success and significant findings from earlier patient outcomes research, coupled with a concern about rising health care costs, led Congress to include language in the Omnibus Budget Reconciliation Act of 1986 which directed the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) "to establish a patient outcome assessment research program to promote research with respect to patient outcomes of selected medical treatments and surgical procedures for the purpose of assessing their appropriateness, necessity and effectiveness."

In carrying out this directive, we are giving priority to medical and surgical treatments and procedures for which (1) the intervention poses a high risk, or offers a high potential benefit to the patient; (2) data indicate a highly variable pattern of provider practices within a distinct geographic area and among different geographic areas; and (3) the intervention is significant in terms of utilization, length of hospital stay, or cost.

These studies have thus far involved procedures utilized by Medicare beneficiaries. A total of 13 multi-year studies have been supported so far, in areas including heart disease, hypertension, diabetes, rheumatoid arthritis, coronary artery bypass surgery, intensive care therapy as well as the prostatectomy study I outlined above. The results of these studies will become known over the next two years.

This year, we will spend approximately $6 million to support both investigator-initiated research and in-depth multi-disciplinary studies of significant or controversial medical treatment effectiveness issues. These latter projects will serve as a basis for developing and testing feasible and acceptable methods for reducing inappropriate variations in the use of medical and surgical procedures. Ultimately, this research will lead to the development of patient outcome information necessary for decision making that will improve quality of care.

Beginning in 1987, and continuing to date, the Department has moved rapidly to make its unique information resources available to effectiveness researchers, in and out of government. This has been done with the benefit of extensive consultation with the medical community and other leaders in health care. The potential for much research already has been demonstrated, such as the comparisons of the effectiveness of coronary artery bypass grafting and balloon angioplasty.

PATIENT OUTCOMES RESEARCH

Our FY 1990 initiative would permit us to use our previous experiences, and to begin building a system that - over the long term - reduces, and may even eliminate, inappropriate health care, while controlling costs. Among the previous programs that will lead us in this direction is patient outcomes research. Begun in 1988, patient outcomes research focused exclusively on evaluation of treatments and procedures for the Medicare population. While the immediate research agenda for our initiative also will have direct relevance to this population, the significant expansion we are proposing will allow us to research such areas as hysterectomy, Caesarian delivery, otitis media, dental implants, and other procedures which, though used on patients of all ages, might have unique risks and benefits in younger populations. Multi-disciplinary research groups will be supported, which will include practicing physicians besides technical experts, and we will continue to support a variety of investigator-initiated studies.

The Department has also recently developed Medicare data on rates of discharges, post-admission deaths and re-hospitalizations for common medical conditions and surgical procedures. Allow me to share with you at least one of our findings. The national rate of coronary artery bypass graft operations is 2.7 per 1,000. Many communities varied considerably from this average, with one community experiencing a rate of only .93 per 1,000 and another experiencing a rate of 5.48 per 1,000. Clearly, we want to know more about these communities, and why their patterns of medical care are so different.

COLLECTION, DEVELOPMENT, AND ANALYSIS OF DATA

Valid and accessible data are a necessity for medical effectiveness research. As the largest health insurer in the nation, HHS has unique access to clinical and billing data from the Medicare program. The Department is eager to make it available for effectiveness research. We have begun the process of merging Medicare parts A and B data, thus providing researchers with more complete information on which to base effectiveness research. Data linkages are being established among HHS data bases such as the cancer registry and the End State Renal Disease Registry. In addition, we will be looking at Medicaid, illness registry, and cohort data bases.

With the assistance of several Peer Review Organizations and practicing physicians, HHS is developing a uniform clinical data set. This data set, while originally designed to facilitate the work of PROs in identifying problem providers, will also serve as a vehicle for systematically collecting information to be used in effectiveness research.

DISSEMINATION OF RESEARCH RESULTS

As medical treatment effectiveness research is completed, the results will be disseminated widely to patients, physicians, payers, and others. The ultimate uses of such research findings are the practicing physician community, who can employ this information to make better informed decisions about patient care, and patients themselves, who want to assess their own potential outcomes and make educated decisions about their health care. Research suggests that physicians want to practice good medicine and will change their behavior voluntarily when informed about findings of relevant patient outcome research. Our effectiveness activity must capitalize to the extent feasible on this physician willingness to change, as well as on the desire of the public to be informed.

The Department will assure that research results are transferred to practitioners through professional organizations and journal publications, public education, and by helping to integrate the findings of the research into medical education. Medical school faculties, who both train new physicians and provide continuing education to practicing providers and academicians, comprise an important audience for the findings of patient outcomes research. We also can assist in developing teaching materials and influencing curriculum development.

The practicing medical community is demonstrating that one important use for effectiveness research is the development of systems of advice for physicians. These are called "parameters", "guidelines", or "standards", by various leaders in the field. The American College of Physicians has pioneered this effort, and the American Medical Association is now playing a vital role. It is especially important that these be written by practicing doctors and not by government bureaucrats.

OUTSIDE CONSULTATION

Our consultation with the outside community has been, and will continue to be, very important to the success of this initiative. We recognize that cooperation with the medical community and with academic institutions that train health care providers is essential. The best way to achieve collaboration is to involve those who will later be using the information in each stage of the process.

With this in mind, we have held a number of conferences and meetings to involve a variety of individuals and organizations in discussions of a range of topics, including the best approaches to such an initiative; the most effective ways to achieve both broad dissemination of research results and their appropriate incorporation into medical practice; and the procedures, treatments, or interventions that need our attention.

The Department is working with components of the National Academy of Sciences, including the Institute of Medicine, to help define priorities for the effectiveness research agenda. In addition, we are proceeding with activities necessary to establish an appropriate medical treatment effectiveness advisory council. We believe that such a council will provide a critical link between the Department and the outside community. The advisory council will serve many functions including assisting us in setting directions for our programs, assuring that we take advantage of merging opportunities, and helping us to ensure the highest quality research possible.

We include consumers and consumer organizations among those who need and can use the findings from effectiveness research and who should be involved in setting priorities and developing strategies for how to get the information to the public. We anticipate that what is learned through this research will help consumers ask the right questions of their providers before undergoing medical treatment and will help them make informed decisions about their health care.

COMMENTS ON THE LEGISLATION

Let me turn now to a discussion of your bill, H.R. 1692. As I look at this legislation, I am struck by the fact that its underlying principles reflect many of the principles envisioned by the Administration's proposal. This includes the importance of medical treatment effectiveness research, data development and information dissemination, and how the department should manage its activities in this area. While I appreciate these similarities, I think it also is important to note, however, that the activities that would be authorized by the bill can be carried out under our current authorities.

The bill acknowledges the need for flexibility in determining roles to be played in the initiative by the various components of the Department; it provides authority for the Secretary to carry out a program without defining in statute which component of the Department will perform which part of the task. At the same time, the bill recognizes that two of the key requirements for success are careful coordination within the Department and involvement of the medical community, in an advisory capacity, so that we will achieve the essential goal of acceptance by practitioners.

As you do in your bill, we place a high premium on disseminating our research results and educating health care providers. Finally, the bill illustrates that you recognize, as we did in developing the FY 1990 budget, that to accomplish the critical objectives of such a program - to have a meaningful impact on health care - requires a significant increase over the previous funding levels.

Let me be a bit more specific about some of the provisions of H.R. 1692. Section 3 of the bill authorizes a program of research very similar to what we have proposed in our FY 1990 budget, without prescribing where within the Department the described activities should be carried out. As each month passes, I find new reasons to be impressed by the unique and versatile resources and abilities of the components of HHS, and I want to be able to employ those resources to the best advantage of the Department and its constituents. H.R. 1692 would allow me that flexibility.

Also, I agree, with the benefit of common formats and uniform definitions for the collection and maintenance of information as described in the bill. I would be concerned, however, about an inflexible requirement to apply the same rigid standards to all data systems. It is possible, it seems to me, to envision cases which are somehow out of the ordinary and which might not easily be standardized, and I would ask you to discuss that matter further with my staff. I find the bill's provisions relating to information dissemination, the development of an advisory council, and an intradepartmental coordinating committee to be generally consistent with our current activities and approaches.

Two of my concerns about H.R. 1692 relate to the bill's requirements for developing medical practice guidelines and to its funding levels and allocation.

I am well aware of the staggering increases in health care costs. And I agree that, over the long term, a better understanding of the appropriateness and effectiveness of medical treatments should lead to targeting spending for better value health care. However, I believe we must be careful not to view effectiveness research, with its promise of long-term benefits, as a short-term panacea for controlling volume or containing costs.

We are proposing a major expansion of our previous effort because we recognize the need for better information. Time is needed to ascertain the extent to which this information actually will improve medical care and whether and how much this will result in cost reductions. Secondly, I believe it would take at least several years - and possibly considerably longer than that - to connect research findings to medical practice.

With respect to the funding of this initiative, we believe that the funds we have requested in our 1990 budget, a total of $52 million ($24 million in new budget authority and $28 million from the Medicare trust funds), are sufficient to launch the medical treatment effectiveness initiative. This represents an almost tenfold expansion over current spending - a major increase, especially in light of many other priorities of the Department and the national budget deficit. I am also concerned that the authorization provided in subsection (g) with respect to the trust funds could be read as a direct appropriation for FY 1990, adding to the level recommended in the President's FY 1990 Budget.

Your legislation is quite specific about how funds would be allocated to the various components of the initiative. For example, your bill would specify the proportional allocation of funds for research, standards development, practice guidelines development, and education and dissemination. Such a formula allocation would hinder flexibility. For example, I am not yet certain what percentage of funds should be allocated to research versus information dissemination and education. As there must be a substantial research base from which to launch an education/information effort, we are not yet in a position to begin that aspect of the program. We have just begun to develop the required base of knowledge.

In closing, Mr. Chairman, I would like to echo the cautionary note of a former HCFA Administrator: "everyone must realize that better information about the effectiveness of interventions cannot answer the question of how much our society should spend on health care. This question can be answered only examining our values and making difficult choices, both in government and in the private sector."

I want to congratulate you on your thoughtful, well-considered approach to this issue which has the potential for making a significant contribution to American health care. I am pleased to have had the opportunity to describe our initiative to you - an initiative that is rooted in our recognition of a need for better understanding of what works best in the practice of medicine. I look forward to continuing to work with you and the Subcommittee as together we seek the goal of effective health care for all of our citizens.

Chairman STARK. Mr. Gradison.

Mr. GRADISON. Thank you, Mr. Chairman, and thank you, Mr. Secretary. It is indeed encouraging to see the broad areas of agreement which exists between the administration and these bills.

Certainly the bills that have been introduced are our first step and can be improved with your help. I particularly appreciate your offer to make your technical people available to work with us, to attempt to perfect these bills and get them in a satisfactory condition. Since we may be moving in a matter of weeks because of the requirements of the budget act on a package, I hope that that can be done quickly, and certainly appreciate your offer of assistance along those lines.

I think it is wise to approach this with caution, which frankly is what I think you have done. I think we have got to avoid overpromising, particularly with regard to the speed with which these research efforts can be undertaken and concluded, and the speed with which the findings, whatever they may be, can be implemented through changes in practice patterns which is a rather long, slow educational matter as near as I can understand it.

One thing that has struck me as I have talked to people about this on the outside as well as the inside of the Government is that a lot of the records which are available may not be coded in a proper manner to the rock-hard use for research purposes, and as well, a lot of the records appear to deal with episodes of care rather than care over a long period of time, which is what we really need in order to make a decision with regard to whether a particular procedure is the best one to use in a specific case. Research like that might require a followup many years after, for example, a surgical procedure has been concluded.

Can you give us any idea, based upon your own research and your own experiences, as far as what the status of the data is in broad terms? Is this question about coding a major concern or do we have to go through a couple of years of trying to get somewhat more uniformity in coding before we can do much with the data that is available?

Secretary SULLIVAN. Thank you, Mr. Gradison. I am going to ask Mr. Hayes to respond to that question.

Mr. GRADISON. Thank you.

Mr. HAYES. Well, Mr. Gradison, we have already in our possession a significant amount of very useful data on 33 million Medicare beneficiaries as well as certain other data bases, as well.

The problem with coding is most particularly true with regard to the more recent requirement that physicians claims, doctor bills to Medicare under part B include the appropriate diagnostic code. That is a requirement that was recently enacted as part of the catastrophic health insurance legislation. It just went into effect on April 1.

Certainly with respect to accurate information in diagnostic coding on part B, that is a genuine problem, and it may take a couple of years to make sure that that diagnostic coding information is fully accurate.

On the other hand, fortunately, we do have quite good information from our Medicare claims data from both part A and part B, which has been and is being used right now by researchers both

inside and outside of the Department, and has been quite valuable and useful.

The situation today is quite good but it will get even better as we get the part B diagnostic coding.

Mr. GRADISON. I want to thank you for that information. That is more encouraging than I had expected, and I am delighted to hear it.

Certainly, if these efforts are to bear fruit, they have got to be done in a way which the practitioners consider to be solid research based, not budgetdriven, and as a result it seems terribly important to me that those carrying out the research are folks at the medical community, particularly the specialties and subspecialties have confidence in.

Sometimes I regret to say the Federal Government, and I mean all of us together, not just HCFA, is viewed as the enemy. We do have a few laws on the books that are pretty abrasive as far as practitioners are concerned.

I wonder, therefore, whether it would be your expectation that a substantial, perhaps a majority of the funds made available for this would be done on an extramural basis which would permit people, even in the specialties and subspecialties or even some of their organizations to come in and apply if they wish to do so to be the principal investigators in carrying out some of this research?

Secretary SULLIVAN. I believe that a majority of the studies that have been funded by the Department, are being performed by outside organizations. We would certainly anticipate continuing to have involvement of a variety of outside investigators.

We are interested in getting the best possible information so we would certainly welcome having the best minds available to work with us to get the answers.

Mr. GRADISON. One final question, Mr. Chairman.

Mr. Secretary, could you specify for me how you would like to see this structured? That is, who within the Department—I mean which office—would be responsible for overseeing the total program which, I would envision from what you said, involve quite a few different parts of the Department of Health and Human Services?

Secretary SULLIVAN. Yes, Mr. Gradison. That individual, actually, is Dr. Mason, the Assistant Secretary for Health who will be responsible for coordinating the work of the Public Health Service, working with his colleagues in our National Center for Health Services Research, the Health Care Finance Administration, and other parts of the Department.

Indeed, you are quite correct. This would be a coordinated effort involving different components of the Department.

Dr. MASON. We see this as a continuation of activities that have been carried out over the past 15 years, and I do not mean business as usual when I say continuation because I think both Congress as well as the executive branch of Government is clearly aware that we need to pursue this aggressively and vigorously.

I agree also with the statement you have made that this must be science based. This is as much research and science-based product as is biomedical research. So we have the tradition of NIH and ADAMHA peer review study sections so that both intramural as

well as extramural research will be carried out under the best aspects of good science-based research including the tradition of NIH and ADAMHA peer review study sections.

The Secretary has asked us to look at our organizational structure that incorporate components of HRSA, of the National Center for Health Services Research, the consensus conference at NIH, the abilities of the Library of Medicine to get information out on automatic electronic data bases.

So I think there are a lot of opportunities for us to even accelerate what has happened in the past.

Mr. GRADISON. Well, thank you, Doctor. That is very helpful. I sense from what you said that you approach this with an attitude, if you will, a sense of excitement about the possibilities of it, and I really deeply appreciate your comments and knowing that you will be taking the lead in this very important effort.

Thanks to all of the witnesses, and thank you for your patience, Mr. Chairman.

Chairman STARK. Thank you. Thank you, Doctor.

Seeing, as was the case of the catastrophic benefits bill and this bill, which is really Mr. Gradison's work, I feel it necessary to play the conservative devil's advocate just to make sure this is all on the level.

I know that you mentioned, Dr. Sullivan, the importance of this research being used in medical school curriculums, and it was mentioned by one of the witnesses that this would be useful in research.

Is there a way, as the devil's advocate, that this could not be done by an existing system? Is there in place, either through academic research or through commercial research being performed by pharmaceutical companies or through the research done in hospitals today that this already exists, and are we sure that we are not just building a bureaucracy here to duplicate something that exists elsewhere?

Secretary SULLIVAN. Thank you, Mr. Chairman.

We do not envision building a separate bureaucracy or a separate research process, no. We envision using the existing organizations that have, first of all, a research culture to organize the protocols in such a way that we will end up with specific answers, including appropriate evaluation mechanisms and peer review as Dr. Mason has mentioned.

Because within hospitals and medical schools, many of the same faculty would be involved in bench research, also would be involved in patient care activities. They would use some of the same talents and skills and orientation as in their blinded clinical studies. The questions that we are concerned about here too, that's scientific rigor.

So we are not envisioning setting up a separate process or different people. We will be emphasizing and focusing a lot more of our efforts on patient outcomes research.

So we see a shift somewhat in the orientation within those research organizations to focusing more on these efforts.

Chairman STARK. I appreciate that answer. Let me push you just one step further and say, even for collecting the data, would it be your view that this could only be done or best be done, either—

those are two levels—in actually collecting the data or why not contract it out to the—what we have, 13 or so intermediaries who now collect a lot of data for us anyway. Again I'm playing the Devil's advocate here.

Secretary SULLIVAN. Yes, I am going to ask Mr. Hayes to comment on that. But we actually believe that the system that we have in place for Medicare beneficiaries and other health programs will work well in collecting the data, though we look for ways to improve it. We will make that data available to various investigators to analyze it when we are looking at various questions.

But I am going to see if Mr. Hayes would want to add to that.

Mr. HAYES. Dr. Sullivan was correct, and I think it's important to distinguish between the function of collecting the data and then using the data.

The Health Care Financing Administration, by definition, has a wealth of data coming in, I might add, from some 90 Medicare contractors, not unfortunately 13, on 33 million beneficiaries, 500 million claims a year on average.

So we collect that data. We also have a wealth of clinical data obtained through the 50 peer review organizations in each State. We are now and intend to expand our efforts in making that data available in a usable version to qualified health services researchers. So I think it is appropriate for us to collect the data and make some use of that with our own analysts and researchers but, very importantly, to make it available in a useful fashion to external qualified research organizations.

Secretary SULLIVAN. Also, Mr. Chairman, I would like to have Dr. Mason respond to that as well.

Dr. MASON. I think the data base is exceedingly important and, of course, this kind of research can't be carried out without a strong comprehensive data base. And we appreciate so much within the Public Health Service this opportunity to work closely with the Health Care Financing Administration.

In the current proposal to increase the budget to $52 million, as you know, a sizable proportion of that money will come from the Medicare trust fund, and will be contracted back from the Public Health Service to the Health Care Financing Administration so that they will have money to put together in a more comprehensive way those data bases that already exist.

So I think we are going to have something that we have never had in the past.

On the other hand, we also need to look at other data bases, comprehensive hospital discharge data. And so we will want to tap in through the National Center for Health Statistics to other sources of data which can complement the information that Health Care Financing Administration has.

We are interested not just in comparing one drug with another drug or one surgical procedure with another surgical procedure, but compare systems of medical practice. So we want to take a broader systems approach, and this will take broad data sets that will have to be pulled from all sectors of the medical community.

Chairman STARK. Dr. Mason, what a marvelous answer. I will now throw away my conservative mantle and get down to business, what I really wanted to talk about anyway.

A short venture into that arena. I do want to ask the panel their reaction to my concern about where we are in the data base world. Because I think we are, without any legislative help, but with some cooperation, I think, on the brink of a new era.

I think it is safe to say that there has been a concern back in several administrations, certainly ever since I've been in Washington, that collecting data by the Federal service somehow has some problems. One, it will create bureaucracies. Two, it sort of intrudes on free enterprise. We ought to contract a lot of that out with 90 intermediaries. There's a fear of interference with medical practice that if we kind of collect data about what the doctor is doing or prescribing, why, we'll start telling the doctor what to do or prescribe.

From the liberal side of the spectrum, there have been great cries of privacy, protection of privacy, interference with personal liberties, that sort of thing. But there have also been some problems. We lost $200 to $500 million I think. We are suing to get some of that back because we couldn't track the primary payer under Medicare claims. I don't know whose fault that was. But I don't think anybody is stealing it. I just think the money is gone.

Perhaps if the data base were more thoroughly integrated, we would have caught that. We are going to be collecting data now for prescription drugs, as you mentioned, because of the need to keep track of each drug. And that may lead to aiding pharmacists in warning people away from drugs that could be harmful. There's some benefit there.

The payment data that we're going to need under the catastrophic bill to see when people have reached their threshold and no longer will be required to copay is going to have to be collected.

A great number of us are interested, as we look at future benefits, long-term care and so forth, and relating that to income. The amount you pay might be related to your income. Very difficult. Very thorny patch to get in. But still an idea that many of us have dealt with.

So what I'm suggesting is, and I understand that we resolved the issue of who pays for the phone call from the pharmacist, but if we could all agree that the time has come to address the concerns I mentioned, keeping the bureaucracy as efficient as we can, and letting free enterprise do what it can, and preserving as best we can the right to privacy, balancing that with the need to know for better research that we ought to look to make this data base as comprehensive and as integrated and as easily interfaceable with whether it's income concerns, because we might very well want to study the effects of various outcomes research on poor people who may not have had as good medical care. And there may be a whole wealth of information there that will be useful to all of us.

I would just urge your administration, which has probably the largest collection of data of any of our Federal bureaucracies, other than perhaps say the Department of Defense, to work with us. If legislation is needed, I assure you this committee will work toward that end to see that we do this right, and we get as comprehensive data and as useful data as we can. Because I think this begins to take on a magnitude that will be of great importance to all of us in the research of a host of areas. And I commend your Department,

Dr. Sullivan, for their willingness to look at this as a real opportunity to break into a frontier that has somewhat been compartmentalized before.

I hope this doesn't scare you, this grand scheme of mine. I would like you to comment. Is there a chance that we could get to a second phase here and get more comprehensive with all of this medical/social data that we have available to us through your Department?

Secretary SULLIVAN. Thank you, Mr. Chairman.

I have several comments to make here. Certainly I would concur with the desire not to create a blow to bureaucracy that I don't think anyone wants, including our Department.

But I think there are several things. I would say that first is the fact that although we spend the largest sum per capita on health care of any industrialized nation, we really have significant gaps in health status. It means that, in spite of our advanced technology, and the fact that American medicine at its best has no peer around the globe, we have some very severe problems in terms of the health status of the poor and minority populations. And we also know that, in spite of having all of those expenditures in many indices, we do not rank No. 1 in the world in terms of health status.

Our desire in the Department is twofold. One, because we are the largest payer for health care in the country through our Medicare and Medicaid Programs, and these are public money, we need to ensure that we receive value for those dollars spent, as well as do everything we can to assure the American people that the health care they are receiving is appropriate. That is the purpose of the effectiveness of research.

I think that physicians and other health care providers want to do a good job. They want to make sure that the things that they do are appropriate. The reality is that over the years, we have found that a number of things that we assumed that would be helpful are not. Therefore, since we do have a large network of data that are coming into the Department, primarily to assure that we are receiving value for dollars spent, we can utilize that data for helping us to improve what we are doing. I think that's very appropriate.

On the privacy issue, I am assured by my colleagues in the Department that data is used in such a way that the privacy of the patient is protected. This is not intrusive on the privacy of the patient then.

We think that utilizing this opportunity to improve our practice patterns really will serve the American public, including each citizen, well. So that our intent is certainly not to invade the privacy of the patient, doctor or their relationship, but to help the health providers, hospitals, physicians, and others to do a better job. I think everyone would agree that we can do much better than we have been doing.

And, finally, we believe that the approach that we are proposing allows the health professions themselves to really, through provision of data of what works and what doesn't work, to really give physicians, hospitals, other health providers an opportunity through their own peer review mechanisms to improve the quality care and effectiveness given. So that's our approach, and certainly

we feel that this is a very helpful approach to the citizens of our country and is not intrusive on the practice of medicine.

Chairman STARK. Thank you very much, Doctor.

Mr. Coyne.

Mr. COYNE. I have no questions.

Chairman STARK. Mr. Pickle.

Mr. PICKLE. Thank you, Mr. Chairman.

Dr. Sullivan, I think that we all would agree that research is desirable and needed to try to determine what operations should be performed, or what practice should be followed. And I think everybody would agree that we need this data.

I have the feeling that one of the purposes of the introduction of the bill is to try to find some way to control volume of services. In addition to that, of course, we want to know who is doing what kind of operation, are they needed, and is it medically proper?

But basically we are trying to see how can we control the volume of services, and this study is one of the ways we are looking into. Now, I don't know whether you would say the research is for purposes of controlling the volume or not.

Let's assume that the purpose is not just to control volume, we don't have to argue that. Let's assume that it's not.

What is your opinion then of practice guidelines as an alternative to expenditure targets?

Secretary SULLIVAN. Thank you, Mr. Pickle.

We believe that what we need to have is information as to what works. What is the best possible approach to a particular health problem? That's the primary purpose of the effectiveness of research. And that's also why we have been cautious in the whole question of the long-term cost effectiveness of this project.

Certainly we think that it has the potential for being cost effective or saving money over the long run. But our primary purpose is to find out what works because we do have a large health care system. And if we are doing a number of things to patients that really are not working, are not effective, that means we are not only wasting money, that means we are subjecting our citizens to the risks inherent in medical procedures which are not going to be beneficial to them.

So we believe that we have the opportunity through the effectiveness research with the data that we now have the capability of collecting to help physicians and other health care providers to really get answers to questions which would be very difficult to get without such a large data base.

Mr. PICKLE. Are you saying that you are for the practice guidelines? Do you support that as an approach?

Secretary SULLIVAN. Well, we believe that our role, Mr. Pickle, is to provide the information as to what works and what does not work, and to then have the medical peer review organizations, of which there are a number in hospitals as well as in national organizations, use this information with their own circumstances and their own colleagues to develop what should be the best practice patterns.

We do not see our role as developing practice guidelines within the Department.

Mr. PICKLE. All right. If you did have practice guidelines established, do you think that could be used as a basis for the denial of medical claims?

Secretary SULLIVAN. Well, I'm not sure that I really fully understand the question.

The fact is what we are interested in, rather than practice guidelines, is actually finding out what works. Practice guidelines, as I understand it, really would not be based on the ultimate data base that we will have——

Mr. PICKLE. Well, Dr. Sullivan, I'm trying to say that if we're not trying to control volume alone, and there are a lot of other reasons for this research, do you want to establish practice guidelines as an alternative to target expenditures?

And the next question is, will we then go to some kind of a system of practice guidelines? If it's purely advisory, I guess you'd say that would be helpful. But if it's more than advisory, then aren't we going to really use practice guidelines as a means of denial claims under our Medicare system?

I don't know why that would be a difficult question. It would seem to me that it inevitably follows that if you're going to have "a cookbook list" of guidelines to follow, that you're going to be using them as a means in denial of claims, controlling volume, or the rightness of prescribing treatment.

Do you agree with that?

Secretary SULLIVAN. Well, Mr. Pickle, our goal and desire is not to develop, as I mentioned previously, practice guidelines within the Department.

We think that that would impose strictures without an adequate data base. And concerning how medicine should be practiced, we believe that physicians and other health care providers, if they are given information, which this data base would provide, as to what works and what does not work, that physicians want to do the right thing by their patients. And they will, through their own self-policing organizations, really improve their practice patterns to indeed incorporate those things that work.

Mr. PICKLE. I understand your statement. You do not want to see practice guidelines established as a means of controlling volume; that it could be advisory, and we ought to be careful to keep it that way.

Do you have any suggestion, any alternative for a different approach other than practice guidelines?

Secretary SULLIVAN. Well, again, this is an effort which we believe we should have many different participants in this process. This is not simply a Federal question. This is a question for the private sector, for various organizations. And we do have a system where we have had private review, peer review organizations. We want to preserve that and not move to a Federal-dictated system.

We see our role as providing the information that will help physicians and others make the best decisions, and then utilize this information within their own organizations for improving practice patterns.

Mr. PICKLE. Well, again, I think it's important that we have this data, and this research can lead to better understanding and a

better balance. But, at the same time, once we get this data, what do you do with it?

Secretary SULLIVAN. Well, we make it available to physicians' organizations. We make it available to the public.

Our purpose here in developing the data is to find out what works. We have had already a number of samples of things which we had assumed in the past would be the best approach to a particular health care problem. And we found that now that we have begun to look at these questions that we were in error.

So it is our belief that by utilizing the data that we will be collecting that, indeed, we have a system where the individuals in that system will utilize this data voluntarily to improve their care practice.

Mr. PICKLE. Well, I'll conclude, Mr. Chairman, that I think it's good to have this information. We need the data. But once we receive it, I hope it's not being used as the basis of rigidly saying, all right, you can do one, two, three, four. You can control your hospitalization. You control your services. And we have got to be certain that it isn't set up as a blueprint to control the practice of medicine totally.

We have spent ages trying to find out what is the best medical care. We wouldn't be involved in this if the volume of services hadn't seemed to be getting out of line.

But, as we look for data, to try to understand it, I think we ought to be certain that we are not using it just to control volume alone.

Thank you, Mr. Chairman.

Secretary SULLIVAN. Mr. Pickle, if I could respond, I would like to emphasize the purpose of this is really primarily to find out what works. That is, we're spending more than $100 billion a year of our tax dollars for health care. And we now, as we have learned over the past decade or so, we find that there are some things for which we have spent money where our assumptions that they were helpful to the patients really have been called into question. So, therefore, we think it's appropriate in our efforts to improve the quality of care that citizens receive, and the health status of our population, that indeed we take advantage of the opportunity we have to reexamine these questions so that we can be reassured about those things which do work, as well as finding out those things which don't work.

We want to avoid spending money on ineffective procedures as well as avoiding exposing patients to the risk and inconvenience of inappropriate or ineffective procedures.

Chairman STARK. Thank you.

I am to recognize—Mrs. Johnson, were you going to yield? I recognize Mrs. Johnson and she is going to yield to Mr. Levin.

Mr. LEVIN. Thank you, Mrs. Johnson, for yielding for just a brief question. I appreciate it because I have to go to another hearing.

Dr. Sullivan and your colleagues and to my colleagues, I very much applaud this legislation and understand its emphasis on overutilization. But there is another problem among others in our health care system, and that is the underutilization of certain procedures or certain techniques, especially in an area we sometimes call prevention.

And so, I was just wondering if you might comment briefly on whether you envisaged this legislation as encouraging as well as authorizing the Department to accelerate, as it deems necessary, any research on underutilization where you think it might exist, and the dissemination of information to the medical world about more effective use of preventive health care?

Secretary SULLIVAN. Thank you, Mr. Levin.

I'm going to ask Dr. Mason to respond to that question.

Dr. MASON. We agree totally with your statement, Mr. Levin, about the importance of the integration of preventive services, and to particularly primary health care. Because I think that is the way that we can optimize the value of each dollar spent.

Within the Department, we have been directed, within the Public Health Service, to work very closely with the Health Care Financing Administration, to look at cost-effective interventions. For example, adult immunization. We are currently doing studies with HCFA using their data base to see what is the return on investment with pneumococcal vaccines and influenza vaccines.

So I think that one of the opportunities that we have, is to look at those interventions that will prevent disease or else prevent the progression of disease and to integrate them into the medical care system so that we optimize the value that we get for each dollar. And we are strongly in favor of that process.

Mr. LEVIN. Well, that's encouraging because we talk about the kind of short-term mentality in this country on economic issues. I think we, in the health field, often have the same kind of psychology, and for adults and seniors, as well as others, we often short-change the long-term, preventive treatment because it doesn't appear to be an immediate dollar return.

And so while I very much agree with the emphasis here on over-utilized procedures, I do hope that we, in our society, will really do a much more effective job in preventive areas.

Mr. GRADISON. Will the gentleman yield?

Mr. LEVIN. Yes.

Mr. GRADISON. I want to congratulate you on you statement, and assure you, as the lead sponsor of this bill, that at least this member has not emphasized the potential cost of savings, money savings from this initiative. Some who are backing this legislation are emphasizing the potential cost savings. I'm not among them.

And the reason is simply this: If we look at two communities, and one has five times as many hysterectomies as the other with age and all the other appropriate adjustments, we still don't know whether one has too high a rate or the other one has too low a rate. We just don't know.

And so I think that, in my mind at least, one of the objectives of this initiative is to try to sort out those questions without emphasizing as a goal short-term savings.

Frankly, I don't know whether this will cost money or save money in the long run. And I think it is going to take some years before we have any idea.

Mr. LEVIN. I think it would save money. I think that's one likely result. But if that's the only purpose of this bill it is going to distort, as you say, the overall drive for better health in America.

Thank you, Mrs. Johnson.

Mrs. JOHNSON. Welcome, Dr. Sullivan, and thank you for your thoughtful presentation regarding where the Department's activity and thinking has been, and your plans to better mobilize and focus your resources in the same direction as the bill we examine today.

As usual, the gentleman from Ohio has made a comprehensive proposal and a very realistic one, but I want to pursue the comments of my colleague from Texas, Jake Pickle. I appreciate Mr. Gradison's remarks and, particularly, his comments on data that may reveal different patterns, but not necessarily give us the information as to which pattern is better.

One of the reasons this kind of research is important is because it may be a more rational way to approach some of the cost issues than some of the other measures we have taken to control costs.

For instance, has the Department made any decision about reimbursing for nonionic contrast material. Now, I do not know a lot about this, but I do know that this is a new material that is used in imaging and reduces the chances of an allergic reaction significantly, but costs 10 times as much.

In this instance, the data is available, designating the superiority of this procedure but the cost is higher. If we are not going to return to a cost-driven reimbursement system, then we are going to have to clarify what discretion practitioners have and provide them with some support, perhaps in the way of less vulnerability to liability if they must choose a less expensive, less effective procedure.

We already have information that dramatically contrasts the issue of cost versus quality. At what point does that minimal increment of quality improvement justify its price?

As much as I do not want to see federally developed practice guidelines that restrict reimbursement to a limited number of procedures, I think the nonionic contrast material issue does pose this problem very clearly to us right now if we are going to wait for 2 years for the material's approval. Providers are not going to be willing to handle something that is 10 times the cost of the current procedure, and yet, what are the consequences of their being unwilling to provide that, "better quality" response?

Has your Department begun to struggle with that dilemma, and if so and in general, would you comment on the inevitable implications of patterns of practice research for the reimbursement system?

Secretary SULLIVAN. Thank you, Representative Johnson. I am going to ask Dr. Mason to comment on your question.

Dr. MASON. Thank you, Secretary Sullivan. The reason that our Secretary has made the decision to give the Public Health Service prime responsibility for the effectiveness in outcome research program is to avoid the perception that this is being driven by reimbursement policy.

If it were placed within the Health Care Financing Administration, there would be many providers, particularly, that would perceive that this was being driven by economics, while the Secretary is bound and determined to have this driven by good science and good quality research, and that the cost implications should not be driving the research.

In other words, we ought to be looking at effectiveness and outcomes, and there should be no consideration as to what this will ultimately cost. I think most of us believe that ultimately there will be more savings than there will be increased costs.

But we have to be willing to let the chips fall where they will, and I think that has to be the underpinnings of this whole process—that we will do science-based effectiveness outcome research, and then we will have to look at that as to whether it will increase costs or decrease costs, but I think it is important that it be science based.

Let me come back to practice guidelines and just reassure you and Mr. Pickle who has left that we are not talking about anything new. This has been going on for years, and might I illustrate with immunization of children.

You recognize that we have one immunization recommendation for DPT, polio, measles, and the newer vaccines like hemophilus B and hepatitis B vaccine. These are standard recommendations that every physician in the United States follows, and how did we get it as a standardized condition? By doing effectiveness research, and then a committee, which is sponsored by the Federal Government, the Public Health Service, called the Advisory Committee for Immunization Practices, meets once a quarter, and it has on the committee practitioners, representatives of the American Academy of Pediatrics—the family practitioners.

So you will have the practice people involved, you have the scientists involved, you have lay people involved, and you sit down and they come up with practice recommendations.

Now these are not mandatory, but they become standards of quality medical practice within the Nation as it applies to the immunization of children, and therefore, when a child moves from one State to another, he takes the same immunization card, and it works just as well in one State as another, because the medical profession based upon good science has adopted recommendations that become a basis for medical practice within the Nation.

Now I suspect that many reimbursers of medical care might at least raise a question if someone where giving fewer doses or more doses than were recommended by the Advisory Committee on Immunization Practices, because it would be a basic violation of those standards that have been adopted.

But the physician then has the ability to justify why he is moving outside of those standards. Maybe there is a particular need in that child. So that it finally can get down to what are the individual needs of an individual patient, but there are some parameters and guidelines that come out of good research.

We see that with the consensus conferences that have been held by the National Institutes of Health on a number of different areas—how to care for a patient with this cancer or that cancer? So we are not getting into areas that are new, but which have been part of medical practice for the last 50 years.

Mrs. JOHNSON. Thank you, Dr. Mason. I think that is a particularly instructive and thoughtful example, and I think it indicates why patterns of practice research in the future have to have more policy impact than they have in the past.

We have known for years about the importance of prevention and yet, his knowledge has not driven our appropriations process to the degree that we can guarantee every child in America immunizations.

I am coming to feel that we must knit much more tightly patterns of practice and public policy. If we do that and steer some of our resources more to, in this case, children, we will have the money to make a concrete decision, whether or not to reimburse for nonionic contrast material. Our responsibility as policymakers ultimately must be to allow this to determine where the Federal responsibility lies.

I, as a policymaker, do not want to see that kind of division between science-based research and policymaking continue.

I agree with my colleague from Texas, because ultimately this debate is something that we will have to engage ourselves in ever more seriously in the years ahead. Thank you.

Chairman STARK. Thank you. Mr. Moody.

Mr. MOODY. Thank you. I will try to be brief, Dr. Sullivan. I know you have other pressing commitments, and I followed this conversation with Mr. Levin and Mr. Pickle and Mrs. Johnson with a great deal of interest.

It seems to me that one of the chief problems in America today is to allocate our medical dollars more effectively and more appropriately. We have only a certain amount of money that we are going to put into medicine at a given time, and while that grows, it is always going to be short of what we might like. We have cases where we are paying a lot of money for relatively marginal procedures, and meanwhile, we have a lot of people in America who are not getting help at all.

So reallocation seems to me to be the No. 1 problem facing us. In that context, obviously the goal, therefore, should be to steer dollars away from less effective and/or more expensive procedures into more effective and less expensive procedures in some combination.

It seems to me that what you are looking at here has got to have an economic component to it. I know Mr. Gradison and Mr. Levin said that we do not want to just look at the economics, but the economics are so important when we have so many unmet needs. We are already spending 12 percent, the highest of any industrialized Nation, on medical care, and yet, we have really an unacceptable level of unmet needs.

To ignore allocation questions is irresponsible. It would certainly be heartless, and so I think that is the key that we, at least in a committee like this, have got to think about.

So I would hope that this study would have an economic component. Then we are talking about between things that have various results some positive and less expensive than others or less positive and more expensive. How you combine that has got to be obviously in the hands of the doctors. We do not want to do that.

But unless a coronary artery bypass—which is twice as likely to happen in New Haven as it is in Boston—is actually a negative event for somebody—and it might be, but assume it is positive—we are wasting a lot of money apparently.

So I do not think you can divorce the effectiveness question—the scientific, to use your colleague's expression—off from the economic question. They have got to go hand in hand to come to outcomes that make sense. Do you want to comment on that?

Secretary SULLIVAN. Yes, Mr. Moody, thank you. Certainly when everything has been completed, there are going to be economic considerations or questions that have to be addressed, but we feel that before we get to that question, we need to find out whether the things that we are doing are proper, are correct.

That is, whether caesarian section, done as often as it is with the various indications, whether those individuals, those mothers and those babies are better off for a caesarian section, or whether tonsillectomies that are done, whether they are required, et cetera.

So our first question is: Is there a way we can improve the health outcomes in our population? We think that is the first question. We think that is our primary question. Then, once we have those data, we think then the second question would be raised as to what would be the appropriate expenditure of dollars.

Our premise is that if we find that some of the things that we are doing are not effective, then those should be eliminated, because there we not only save money, but more importantly, we avoid risking our citizens to the dangers of those procedures.

Every time anesthesia is given, there is always a risk of an adverse outcome, even though remote, but you multiply that thousands of times during the year, we could really see the health effects of that.

When we give medicines, by and large we expect to have a good outcome, but there are unavoidable statistical likelihoods of an adverse reaction to a drug. So if we find that that drug is really not helpful, then we will avoid exposing that patient to that drug with whatever risk is attendant.

Now we would save money there too, but we feel that we have a large system, and we have enough questions about the things that we are doing that we need to first of all examine whether what we are doing is correct.

As mentioned earlier, we do feel that it is a great likelihood that moneys would be saved here, but that is not our first question here. The first question is: Are we getting values for the dollars that we are spending now, and are the things that we are doing now the correct ones?

Mr. MOODY. Is not the question of spending inherently an allocation question?

Let us do as Professor Hsiao did, try to find some objective measurement to something. Let us say procedure A provides 10 units of benefit, and procedure B provides 15, and there are substitutes. You do not do both on the same patient.

Say procedure B is twice as expensive as procedure A. Now you are not saying that both are effective, but one is—and you have to take statistics into account, because you have a lot of large numbers that work here, but let us say on balance or statistically that the procedure B is twice as expensive, but only half again as effective.

Well, you cannot make a purely scientific decision. You have got to bring economics into the decisionmaking, because we cannot pro-

vide everybody with the most expensive procedure. We might like to if the money were unlimited, but since money is never unlimited, we have got to make those economic/scientific decisions in combination. You cannot make it a purely scientific decision. I guess that is my——

Secretary SULLIVAN. Yes, sir, I would agree with you there, but the only point I was making is that I think in many instances, surprisingly we do not have the data to be sure that what we are doing has any benefit. Now——

Mr. MOODY. It actually might be a negative benefit.

Secretary SULLIVAN. Yes.

Mr. MOODY. Okay, that certainly we can agree to that. We should rule all of those out as soon as possible.

Secretary SULLIVAN. Yes.

Mr. MOODY. But once you get beyond that——

Secretary SULLIVAN. Yes, I would agree, that had been a square judgment. I think that that, again, is a discussion and a debate that would have to be joined, I think, not simply by Health and Human Services, but by the Congress and by other people also. I agree fully with you that that is when the questions are going to become much murkier, but we are not there yet.

Mr. MOODY. So we are in the position of not even knowing whether the effectiveness of some procedures is greater than zero.

Secretary SULLIVAN. Well, when it comes to questions of, say, one community that may have five times as many hysterectomies as another community. The question is: Is that really because that five times greater incidence is really indicated, or is it because the medical community has not looked at that very closely there? It is those questions that we are really looking at.

Mr. MOODY. I agree with all you have said, but to apply the study meaningfully down the road, we are going to have to bring in economics.

Secretary SULLIVAN. Oh yes, I agree.

Mr. MOODY. Thank you.

Chairman STARK. Mr. Anthony.

Mr. ANTHONY. Thank you, Mr. Chairman. I just have one inquiry, Dr. Sullivan. On page 2 of your testimony, you indicate that HHS has been studying this for approximately two decades, and you talk about in other parts of your testimony that you are already doing certain things within the Department that the bill says to do, and you are saying that you can even do it within existing authority.

The part that disturbs me is on page 9 of your testimony, and I will just read one sentence. It says, "Secondly, I believe it would take at least several years and possibly considerably longer than that to connect research findings to medical practice." That is a little bit too hazy for me when you say, "several years and possibly considerably longer" than several years. What disturbs me is you have already made an admission that you have been looking at it for two decades.

My whole concern is: How do we hold down the cost? So I would be looking at it from: Would we be able to bring down some cost saving?

And, Mr. Chairman, this was really brought home to me over Mother's Day weekend. My sister lives in Houston. She brought the Houston paper to my hometown of El Dorado with her, and on the front page was this enormous story that talked about the overutilization of cataract surgery, and that Houston was one of the leading areas for numbers of procedures per thousand.

So up until then, I had not really zeroed in on it. Really, I am just asking you to clarify a little bit more what "several years and considerably longer than that" would mean.

Secretary SULLIVAN. Thank you, Mr. Anthony. Let me first comment to say that we believe that there are a number of other strategies that really should be utilized in the short term to help control costs, hopefully by strong peer review organizations in hospitals and other areas, but what we are saying here is that it does take a significant amount of time to collect the data, to organize it, to analyze it, and then once we have a conclusion to then disseminate that and encourage health providers to change practice patterns. That is a process that takes time, because it means getting individuals to change a behavior that historically it does take, in a most overwhelming number of instances, a lag time between a new finding and then discovering ways to effectively implement that finding.

But I would use one example, let us say, from the general public to show how this happens. We have really known since the early 1960's that smoking causes cancer or is related to high instances of lung cancer, and really it is only in the last 6 or 7 years that the American public has really heard that message to the degree that they have changed behavior in restricting or reducing smoking.

Because while the things that we are saying now were being said back in 1963, that really did not result in a change in behavior for at least a decade or more. Now we do not envision that long a period, but it does mean that when we tell physicians, say, who are used to taking out cataracts with certain indications, that there is a better way, an alternative way. It does take time to get that infused within the medical practice of that group.

So it is really the time for diffusion of that information that results in that.

Mr. ANTHONY. Just a final question: Do you have enough of your key personnel presently on board and working on a day-to-day basis to build and move forward with all deliberate speed on all of these important initiatives? Are you fully staffed?

Secretary SULLIVAN. Well, we certainly are sufficiently staffed to move ahead on this.

Mr. ANTHONY. Are you fully staffed in your key positions?

Secretary SULLIVAN. Well, not completely.

Mr. ANTHONY. How many are you short at the moment?

Secretary SULLIVAN. Of course, we are waiting for the name of our recommended person for HCFA to go forward for confirmation, and that person will play a significant role in this effort, as well as other individuals that he will bring on board.

Dr. Mason has several appointments that he will be concerned with making, such as a new Director of the National Institutes of Health, the Director of Centers for Disease Control, and others. The precise number, we would have to get——

Mr. ANTHONY. Well, you have mentioned three very, very sensitive and important positions, and three positions that this subcommittee and the full Congress would work with. I guess I am kind of getting a growing gnawing feeling in my belly that I do not want there to be a perception that the Congress is a do nothing Congress if, in fact, the people that we are asked to work with are not in place.

So I would just encourage you to try to move that process along as speedily as possible, so that we can work with you to make some of these very important decisions, especially as we have to start marking up our Medicare spending bill.

Thank you, Mr. Chairman. I yield back.

Secretary SULLIVAN. Thank you, Mr. Anthony. I certainly share your concern that we get the positions filled as quickly as possible, but in those positions, we do have individuals such as Mr. Hayes, our Acting HCFA Administrator. We are working, and we are moving forward with this, and we are anxious to move forward and work with you.

Chairman STARK. Thank you very much, Dr. Sullivan and Dr. Mason.

Secretary SULLIVAN. Thank you very much.

Chairman STARK. We appreciate your testimony. Our next witnesses will comprise a panel. Dr. Robert Brook, the deputy director of the health services program of the RAND Corp.; Dr. John Wennberg, professor of epidemiology for the Department of Community and Family Medicine at Dartmouth Medical School; and Dr. Paul Ellwood, the chairman of InterStudy at Excelsior, MN.

Gentlemen, the lights will blink at you to give you an indication of a 5-minute fine period for each of you and the members will also try and inquire within that timeframe. I am sure with your prepared remarks appearing in the record in their entirety, if you could summarize or expand on those for us, and we can then allow you to further expand during the inquiry. The subsequent witnesses will appreciate that, and we welcome you here to the committee.

Please proceed in the order you are called. Dr. Brook, we are pleased to have you here, and would you proceed?

STATEMENT OF ROBERT BROOK, M.D., DEPUTY DIRECTOR, HEALTH SCIENCES PROGRAM, THE RAND CORP. AND CHIEF OF THE DIVISION OF GERIATRICS, PROFESSOR OF MEDICINE AND PUBLIC HEALTH, UCLA CENTER FOR THE HEALTH SCIENCES PROGRAM

Dr. BROOK. Thank you very much. I wish to begin this testimony by thanking you for considering a bill that I think is going to lay a new foundation for the clinical sciences and medicine in the United States.

I would like to speak to you from two perspectives. The first as chief of geriatrics and an internist, and the second as a health services researcher. I have spent the last 20 years or so trying to figure out ways to improve the quality of care.

On one hand, I would like to be dispassionate and suggest that we need to know more about what we do. On the other hand, if and

when you become a patient as opposed to a Member of Congress, you are not exactly going to want me to say, "Wait 20 years until we can figure out what to do before I decide what to do." You are going to demand action, and you are going to ask me to do something today. So, the message I bring you is twofold.

One, we clearly need to know more about what works. Two, we know a lot now that we do not apply correctly; we can measure appropriateness, we can improve what we are doing, and we can do it relatively rapidly if we have the will to do it.

Coming back to the new foundation, I would like to state that in my 20 years in doing health services research, I have been frustrated by determining and discovering that economic solutions to our problems, such as changing the way doctors are paid, capping salaries, or changing financial incentives, do not seem to accomplish our twin objectives of increasing or maintaining quality and at the same time, constraining costs, to a rise that we all can tolerate.

I believe that the only hope for achieving these twin objectives comes from trying to distinguish what part of what we do works from what does not, and then to provide what works to everybody and do not provide what does not work to anybody. To be a little bit more precise, when we did the RAND health insurance experiment, we discovered that when you provided care free to people versus made them pay something out-of-pocket, they consumed more care. Unfortunately, they consumed both care that was needed and care that was not needed. And the net impact for the average person on health 3 years later was no positive or negative impact.

I am not sure that any of you, when you are having your crushing chest pain at home, want to wake up in the middle of the night and decide, well, I have to pay $1,000 before I call my doctor, should I wait another 5 minutes? And by the time you wait 5 minutes, the paramedics are there and not helping you as much as they might have.

We also found that by increasing the amount of care, we also stimulated the use of drugs. The amount of tranquilizers given to the people enrolled in the population increased by about 70 percent; antibiotic use was increased by about the same amount, as well as narcotic use. One way of having a kinder, gentler nation seems to be to provide free care.

Now, what do we know about where we are at the moment? First, I would like to state that in the appropriateness area, we need to know more about what works and does not work. In a joint RAND/UCLA project, we reviewed six procedures, some of them surgical and some of them medical, and looked at the entire scientific literature and found you could not answer questions such as: Does carotid endarterectomy, which is a procedure that is done almost a hundred thousand times a year in this country, work under any conditions? We could not answer questions such as: Does endoscopy, which is a tube that one puts into the stomach, especially in elderly people, work at all when the person presents with mild stomach pain or dyspepsia? And by "works," I mean produces more or less health.

When you try to broaden the questions, it becomes even more difficult; if you came to me as a patient and asked me to tell you

whether and how the use of procedure one versus procedure two would affect things other than your survival, such as your quality of life, I could not answer that question.

Answering these questions will require a pluralistic approach to gathering new information. That information will not be available solely in claims data banks under any circumstances, but will require the linking of data bases, such as the ones you discussed previously, with data obtained from patients on a routine basis. It also will require going beyond just doing this kind of observational research and doing randomized controlled trials.

On the other hand, our work at RAND/UCLA did not stop with evaluating the literature. We found that we knew quite a bit about what was done, and we developed a process by which we combined what was in the literature with what a panel of expert physicians thought we should do, and came up with standards for appropriateness. And we did this using the following major principle: I believe firmly that the standards or the guidelines, or whatever we are going to call them, by which medicine should be practiced must be in the public domain. There is nobody that is going to pay for that activity other than the Federal Government.

If we want a medical system that consumes 12 percent or whatever of our gross national product to be run by standards that are hidden in black boxes and nobody knows what they are, then the Federal Government need not invest in this process at all. If, however, we believe in public standards or guidelines, such as the standards we have for what a pound is, then we are going to need a process that produces those public standards.

When we developed those indications and guidelines and applied them to random samples of patients, mostly Medicare patients, we found a level of inappropriate use of care agreed to by physicians that was much higher than anyone would reasonably want to ignore. We, however, did not study the problem of underuse. It is easier to measure overuse, because you can track what happens to people when they get a service. It is much harder to look at underuse, which is the absence of a procedure that would have been beneficial. We will have to deal with underuse as well, as we change incentives in the health system from fee-for-service to capitated.

The final message is that we are ready to go. We could in the appropriateness area, with a set of academic institutions that we have already put together, probably produce 15 to 20 sets of guidelines for 15 to 20 procedures that consume 20 percent of the charges that physicians make to Medicare within a 2- to 3-year time period.

[The statement of Dr. Brook follows:]

Statement of Robert H. Brook, Deputy Director, Health Services Program, RAND, Corp.

I am Robert H. Brook, Chief of Geriatrics and Professor of Medicine and Public Health at UCLA's Center for the Health Sciences. I am also the Deputy Director of The RAND Health Sciences Program. I currently am serving as Vice President of the Association of Health Services Research.

I wish to begin this testimony with a simple thank you. Thank you for holding hearings on a bill that I believe will lay the foundation for achieving the twin goals of providing all Americans with effective health care while at the same time preventing medical expenditures from accelerating faster than the rate of increase of the Gross National Product.

This bill challenges the medical profession to make the health care system function effectively. It asks the medical profession to determine what part of its arsenal works and what part does not. It asks the profession to use its knowledge about what is efficacious medical care by setting guidelines for practice that will help physicians and patients distinguish what should, from what should not, be done. It even implies that the doctor should do only those things that work to patients (i.e., improves their health) and not do things that do not work. It envisions a time when public money and pretax dollars will not be used to pay for services with unknown or detrimental health effects on patients.

To accomplish these lofty goals requires a new level of cooperation between the public and the medical profession. The determination of what works or does not work must reflect not only objective physiologic findings, but also the public's values. Researchers must ask patients questions about how particular procedures have affected their ability to work, their mood or their sense of well-being. This information must in turn be fed back to doctors so that they can modify practice patterns appropriately.

But why this foundation? Do we not know enough about what works and what does not to take action today? Better yet, can we not achieve our goals by increasing co-insurance rates, capping doctors' fees or eliminating the amount of resources that are consumed by the medical system? Of course we can, but limiting resources without promulgation of clinical standards will not maintain quality. In order to achieve the twin goals of providing effective care for all Americans at a price we can afford, we must develop explicit practice guidelines to help physicians choose among treatment options.

There is evidence to support the rather bold assertion that improving America's health system will require a **clinical** solution linked to an economic one, and not an economic one alone. Economic tools are simply too indiscriminate in their effects.

For example, my colleagues and I, under the direction of Dr. Nicole Lurie, evaluated the impact of the state of California's decision to restructure its Medicaid program. California changed the coverage for care for 270,000 medically indigent adults. We found that, as a direct result of curtailing the insurance status of these poor and sick adults, blood pressure of hypertensive patients rose, blood sugar of diabetic patients became uncontrolled, and the death rate increased relative to a control group.[1,2] Many of these changes were produced because patients simply could no longer afford to buy the medications that were required to control their chronic diseases. We discovered that changes in health policy can kill people and that these changes can have effects that are larger than those achieved from the application of standard medical technologies. For instance, the deaths that resulted from the policy change to restructure the Medicaid program probably exceeded the deaths that would be prevented by screening all California women for breast cancer.

Another example comes from the RAND Health Insurance Experiment, led by Dr. Joseph P. Newhouse. Families residing in six communities in the United States were randomly assigned to health insurance plans that

differed in the amount of out-of-pocket payments they had to make when they received their care. People who were required to pay a share of their medical bills made approximately one-third fewer visits to a physician and were hospitalized about one-third less often than those who had free care.[3] Despite lower utilization, the **average** person at the end of the experiment was no worse off, i.e., was just as healthy, under cost-sharing than with free care. (On the other hand, the poor who were also sick were made slightly worse off by cost-sharing.) However, the result for the average person was achieved by reducing proportionally both appropriate and inappropriate use (i.e., both effective and ineffective care).[4,5] Cost-sharing prevented some people from receiving inappropriate care (i.e., where risk exceeds benefit), but it also prevented some people from receiving beneficial health care. The net effect was no change in health status.

But is this the best we can do? I believe we can and should do better. Can we find a mechanism for controlling costs that is flexible across different clinical situations? I think we can all agree that anyone experiencing a heart attack should have immediate access to care. On the other hand, medical care has little to offer most sufferers of the common cold. Yet many receive inappropriate antibiotics that may cause iatrogenic complications. Distinguishing between these two situations may seem simple, but in the absence of available clinical guidelines many other choices are less clear. To do better, we need to define clinically what is meant by appropriate care and then use those definitions to move the care delivered toward the appropriate end of the spectrum.

For a physician, the word appropriate means that the health benefit expected from performing a procedure exceeds the health risk for that patient by a sufficient degree to make the procedure worth doing. Notice that this definition does not include costs. It is strictly a clinical one. So how does one obtain data about whether a procedure's use is appropriate or inappropriate in a patient with a particular set of symptoms or complaints? One must first review what is known. We at RAND and UCLA began our efforts in this area by reviewing the literature on the use of six procedures: carotid endarterectomy, coronary angiography, coronary artery bypass surgery, cholecystectomy, colonoscopy, and upper GI endoscopy.[6] Not surprisingly, we discovered that much less is known about the uses and benefits of a procedure than one would like. For instance, about 100,000 carotid endarterectomies are performed annually in the United States. The purpose of the procedure is to prevent strokes and deaths in patients who suffer from cerebrovascular disease. However, there is no clear evidence in the literature to support its use. Further, in our medical records study of a random sample of 1,300 Medicare patients who had this procedure in 1981, we found that about 11 percent of those who had the procedure experienced complications (i.e., deaths, heart attacks, strokes).[7] Similarly, there is no literature that supports the use of endoscopy, prior to providing medical therapy, to investigate dyspepsia, or stomach discomfort.

On the other hand, some procedures, such as coronary artery bypass surgery, have been better evaluated. But even in this case, we know relatively little about the efficacy of the use of coronary artery bypass surgery in patients who are old and sick, because these patients are systematically excluded from many of the randomized trials that are performed. Furthermore, such randomized trials rarely include information on the impact of these interventions or procedures on quality of life. Changes in quality of life are certainly of interest to patients, and such information should be available to assist doctors and patients in making decisions about treatments. As a geriatrician and internist, my patients frequently ask what the effect of a particular procedure will be in terms of their energy level, their ability to walk, or their ability to take care of themselves. Very often, I simply cannot provide an informed answer because such information has not been collected.

Our work in the appropriateness area did not end with the statement that we need more knowledge. The knowledge we have is quite extensive and it certainly can be better used. Towards this end, we developed a method to assess appropriateness that relied on doing a literature review, developing a detailed list of potential uses for a procedure and rating these uses (i.e., indications) for their appropriateness.[8] The ratings were performed by a panel of nine physicians, including academicians and private practitioners, specialists who did the procedure and generalists who did not, and physicians from all areas of the country. These panelists, working privately at home, rated all possible uses of a procedure, both appropriate and inappropriate, on a 9-point scale, where 9 meant appropriate and 1 meant inappropriate. The panel then met, discussed their ratings and re-rated all indications. We then published the literature review, the indications, and the ratings. The process we followed in this activity clearly needs improvement. It is like a Model-T. It runs, but it can run better, and knowledge about its reliability and validity needs to be expanded. The sciences of meta-analysis and decision analysis need to be brought to bear on this method of setting standards and guidelines for judging appropriateness.

Nevertheless, we had enough evidence of validity and reliability of the Model-T method of measuring appropriateness to apply the panel's ratings to a large random sample of Medicare patients who received care in five states. We studied the appropriateness of the use of carotid endarterectomy, upper GI endoscopy and coronary angiography among these patients. We also applied the carotid endarterectomy ratings to care received in five academic VA hospitals and applied the coronary artery bypass ratings to care received by patients in three hospitals in a western state. We found the following results: For carotid endarterectomy, 32 percent of cases were inappropriate and 32 percent were equivocal (i.e., neither appropriate nor inappropriate); for endoscopy, the figures were 17 percent and 11 percent respectively; and for coronary angiography, the figures were 17 percent and 8.5 percent, respectively.[9] Thus, if we wanted to disallow payment only for clearly inappropriate care, one-sixth of endoscopies and one-sixth of coronary angiographies would be eliminated as would one-third of carotid endarterectomies. On the other hand, if one believes that public funds should not be used to pay for procedures when their use is of uncertain benefit, then the disallowances would increase to one-fourth, one-fourth, and two-thirds. Results of our study of coronary artery bypass surgery were similar, with 14 percent of the patients having received inappropriate care and 30 percent equivocal care. The percentage of appropriate surgeries varied dramatically by hospital in which the procedure was conducted, from 37 percent to 78 percent.[10] This variation is, of course, not a characteristic of the hospital, but rather is a function of the medical staff that performs the particular procedure. Data from our carotid endarterectomy study in academically associated VA hospitals showed that inappropriate care was high in these hospitals, at about 50%, and this occurred in settings in which physicians were not paid more for doing more procedures.[11]

The findings reported above are consistent with the work of others. They probably represent an underestimate of the level of inappropriate care.[12] In our research work we deliberately erred on the side of labelling the use of a procedure appropriate when the data about its use were in any way ambiguous.

Where do we go from here? We have demonstrated that it is possible to measure appropriateness of care and that, when those measures are applied to patient care, the amount of inappropriateness is too high in terms of both costs (it wastes money) and quality (most procedures can be potentially harmful) to be ignored. Before we decide, using economic tools, to ration care that is truly effective we should consider the alternative suggested by the above information.[13] The next step would be to expand the investigations reported above to the other 50 to 100 procedures that make up much of what we do, while simultaneously making every effort to improve the methods for judging appropriateness in both clinical and health research dimensions. The results of these studies

must be placed promptly in the public domain, available for all to use or critique. In addition, the criteria, standards or guidelines--the rules of judgment--must be frequently updated to reflect changes in our knowledge and advances in science.

We have begun this effort on a small scale by organizing a consortium of nine academic medical centers which have the needed motivation and intellectual leadership in health services research. This organizational activity was made possible under a planning grant from The John A. Hartford Foundation, but to accomplish this work will require the expenditure of far more funds than the Hartford Foundation can devote to this activity.

In addition, we strongly believe that we must not lose sight of the fact that most of the recent work in the area of appropriateness concerns overuse. We must also worry about underuse. For example, blacks receive many fewer invasive cardiac procedures than do whites, yet they appear to have no less heart disease. In addition, as more and more people become enrolled in health maintenance organizations, these people will receive care under circumstances where the financial incentives favor underuse, whereas in the fee-for-service system incentives favor overuse. We thus must be prepared to develop a fair system for judging quality of care and appropriateness in both the HMO and fee-for-service systems. To accomplish this task, we have put together a consortium of 12 HMOs under a separate planning grant from the John A. Hartford Foundation. We have worked with the HMOs to identify target areas for assessing the quality of care they deliver. Eventually, we envision making comparative assessments of quality available to the public. Both the academic medical center and HMO consortiums are ready to begin when you are.

In summary, work in the appropriateness and quality of care areas leads me to believe that:

1. We can measure quality and appropriateness.

2. Major academic institutions are willing to respond to the challenge to measure quality and appropriateness and to release institution-specific information in these areas.

3. We can improve quality and appropriateness of care.

4. We can produce a much better health care system.

To accomplish these objectives in a reasonable timeframe will require the investment of tens of millions of dollars a year and the willingness to improve the methods by which quality and appropriateness are measured. We need to make a strong commitment to place the standards by which medicine will be judged in the public domain. A profession which consumes almost one-eighth of the gross national product of a country cannot be judged by a black box whose contents are known only to a few people. If we commit ourselves to developing detailed standards for the practice of medicine, as well as the methods to apply them, the public can be provided with information about the appropriateness and quality of the care given to them. Similar information can be provided to the profession and to all other interested parties. I believe this effort will help strengthen the health care system and enable us to achieve our goals without going down the path of rationing care that is truly effective.

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Mr. COYNE [presiding]. Thank you.
Dr. Wennberg.

STATEMENT OF JOHN E. WENNBERG, M.D., M.P.H., PROFESSOR OF EPIDEMIOLOGY, DEPARTMENT OF COMMUNITY AND FAMILY MEDICINE, DARTMOUTH MEDICAL SCHOOL, HANOVER, NH

Dr. WENNBERG. Thank you for the opportunity to testify in support of H.R. 1692. This legislation is a clear signal of the resolve of Congress to put an end to unnecessary uncertainty in medicine. This uncertainty is caused by lack of attention to outcomes research and the evaluative clinical sciences. Let me summarize my written testimony on how outcomes research works to improve the scientific and ethical basis of clinical as well as policy decisionmaking.

Over the last 4 years, I have worked with an interdisciplinary team of researchers and practicing physicians evaluating the outcomes of different ways physicians treat benign prostatic hyperplasia, or BPH. This common condition affects many men by the time they reach retirement age. The various treatments of BPH include watchful waiting, surgery, drugs, balloons to dilate the prostate gland, and microwave diathermy. Prior to our work, no one had been concerned with the systematic comparison of the outcomes of these treatments, even though more than 350,000 prostatectomies are performed in this country at a cost of about $4 billion.

The result of this neglect is great scientific uncertainty about the best treatment. This uncertainty is reflected in the wide variations in the chances that a patient will undergo this operation. In some communities, over 50 percent of men undergo this operation, while in others the chances can be as low as 10 percent, five times lower.

We now know why the variations occur. Some physicians believe the operation should be performed early in the course of the disease to improve life expectancy. Others believe that, for most patients, the primary reason for undertaking the operation is to reduce symptoms and improve the quality of life. We tested this difference in theory to show that early operation does not improve life expectancy. We studied all the outcomes that are relevant to patients, including the chances for improvement in symptoms and quality of life, and the downside risks, such as impotence and incontinence. We found that some patients, even though they were severely symptomatic, preferred not to have the operation because they were not overly bothered by their symptoms, or else they wanted to avoid the risk of operation.

We concluded that rational decisionmaking in the choice of treatment for BPH depends on patient attitudes toward risk and outcomes and, therefore, requires the active engagement of the patient in the decisionmaking. We are making the results of our assessment available so patients and physicians can use them in actual clinical practice.

Our assessment team views its mandate broadly to evaluate all relevant theory and treatments, the old and the new. We have uncovered evidence that an older way of doing prostate operations, the open prostatectomy, may be better than the newer way. May. The transurethral prostatectomy, even though it is now the stand-

ard practice, may have higher long-term complication rates in the years following operation, including mortality. We have recommended a prospective randomized clinical trial to establish if there are true differences between these operations, and we are very pleased that the American Urologic Association leadership has accepted this recommendation. We are now meeting with urologists in North America and Europe to plan this study.

Our experience indicates some of the impacts this legislation can have. The fundamental impact will be improvement in the scientific basis for clinical decisionmaking and policy decisionmaking. It will make it possible for individual patients to make medical choices that reflect their own preferences based on information about the risks and benefits of alternative treatments. It will make it possible to base resource allocation on information about outcomes and avoid an uninformed debate about rationing, in which no one really knows the outcomes of treatments regardless of their costs.

The legislation will also have an important impact on medical education in the research community. There is an intellectual crisis in the scientific basis in medicine. This crisis is reflected in the wide variations in use of care and the growing evidence that much of medical theory is untested. As a response to this crisis, we are now witnessing the emergence of a new medical science, the evaluative clinical sciences, a set of disciplines distinct from the biomedical sciences. The role of the evaluative clinical sciences is to evaluate medical theories and improve the possibilities for active and informed patient participation in the medical decision process.

The strengthening of evaluative clinical sciences in the Nation's medical schools will be an important result of this legislation. Thank you very much.

[The statement of Dr. Wennberg follows:]

STATEMENT OF JOHN E. WENNBERG, M.D., DARTMOUTH MEDICAL SCHOOL

Thank you for the opportunity to testify in support of H.R. 1692.

The passage of this legislation by the House of Representatives will be a clear signal of the resolve of Congress to put an end to unnecessary uncertainty in medicine caused by lack of attention to outcomes research and the evaluative clinical sciences. The thalidomide tragedy of the 1960's galvanized this nation's determination to test the efficacy of drugs, but we have neglected the equally important need to apply the ethic of evaluation to the use of hospitals, surgery, diagnostic tests and other treatments physicians use routinely in their practices. As a result, there is a double standard for truth that compromises the scientific basis for decision making in clinical medicine. H.R. 1692 and its counterpart in the Senate introduced by Senator Mitchell greatly increases the support for outcomes research. **Passage of this legislation is a very important step in establishing the evaluative clinical sciences as a force for improving the scientific basis for clinical and policy decision making in medicine.** In my testimony I highlight why it is important to undertake this research and give an example of how outcomes research works to reduce uncertainty and to improve the scientific and ethical basis for clinical decision making. I close by discussing the principles that must be followed if the evaluative clinical sciences are to succeed in their mission.

Why Is Outcomes Research Needed?

We need answers to a number of unresolved clinical hypotheses about the effects of treatment which, left unexamined, compromise the rationality of clinical medicine and reduce the status of physicians and the confidence of patients and make rational decisions on the allocation of resources impossible.

For example:

The last few years have seen the rapid proliferation of medical theories concerning the best way to treat chest pain caused by impeded blood flow in the artery that feeds the muscle of the heart. Some physicians recommend surgery--the well-known coronary bypass operation. Others recommend coronary artery angioplasty--the insertion of a balloon catheter into the heart's artery which is then expanded to reduce the obstruction. Still others recommend drug treatment. Debates about the relative value of these different treatments rage in clinical medicine, but because the outcomes are not systematically compared, the debates cannot be settled.

There are new ways to treat arthritis of the hip and knee. One approach involves the surgical replacement of the hip or knee joint and for physicians and patients who choose this method there are a number of alternative ways of accomplishing the replacement. There are many choices but no consensus on which approach is best for the patient. There

is also considerable disagreement about when in the natural history of the disease the operation should be planned if at all. These differences in opinion translate into costly differences in the rates at which various services are performed in different parts of the country. The National Center's Outcome Assessment Program is designed to develop the scientific information needed to settle these controversies.

The evaluation of the outcomes of clinically different approaches to treating common medical conditions such as back pain, pneumonia and gastrointestinal disease is perhaps the most neglected area of all. In many communities in this country, physicians favor the outpatient setting for treating these patients, while in other communities the standards of practice favor the use of hospitals. Similar uncertainties and controversies about correct practice exist concerning the value of intensive care units.

Neglect of these and a host of similar uncertainties and controversies about the scientifically and ethically correct way to practice medicine has enormous consequences for patient well-being and for the health care economy. Unresolved discrepancies in medical theory are responsible for much of the practice-style-driven influences on demand that affect the cost and use of care, even in medically sophisticated communities such as Boston and New Haven.

Consider Boston and New Haven, which are renowned centers of academic excellence in medicine.[1] The residents of these two communities are remarkably similar in demographic characteristics that predict the need for care. They receive virtually all of their medical care from physicians affiliated with some of the nation's finest medical schools. By definition, the medicine in these communities must be viewed as state-of-the-art. But how different is the state-of-the-art of medical thinking in these two communities, viewed from the perspective of what happens to patients?

Residents of New Haven are about twice as likely to undergo a bypass operation for coronary artery disease as their counterparts in Boston who are more likely to be treated by other means. On the other hand, Bostonians are much more likely to have their hips and knees replaced by a surgical prosthesis than are New Havenites whose physicians tend to prescribe medical treatments for these conditions. Bostonians are more than twice as likely to have a carotid endarterectomy--the controversial operation undertaken on the theory that it is the best way to prevent strokes arising from disease of the artery in the neck--while clinicians in New Haven appear to prefer medical management involving the daily use of aspirin or other drugs. By contrast, hysterectomies for non-cancerous conditions of the uterus are more commonly performed on New Havenites.

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Most significant for the costs of medical care, Bostonians are much more likely to be hospitalized for medical conditions than are New Haven residents. In 1982, Medicare reimbursements for hospitals were $1,894 in Boston per person, while in New Haven they were $1,078. Differences such as these are seen year in and year out. If New Haven reimbursements had applied to the 78,000 enrollees living in Boston, the outlays would have been $63 million less--$85 million rather than the actual $148 million. Decisions on the best place to treat a host of acute and chronic medical conditions--the most common and costly examples of the differences are the treatment of low back pain, pneumonia and gastroenteritis--account for much of the difference in total per capita costs for medical care between these two communities.

These statistics of variation carry broad implications. **For many common conditions, the academic standards for medical practice as now constituted are not based on well tested medical theory.** Physicians, patients, those who pay for care and those in policy positions remain ignorant of the health care outcome consequences of spending vastly different proportions of the gross national product (GNP) on health care. The Boston-New Haven comparison shows that the scientific basis of medicine as now constituted does not understand the significance of an investment of upwards of 16 percent of GNP (as for Bostonians) from 9 percent (as for New Havenites).

An Example of Outcomes Research: Treatments for Benign Prostatic Hyperplasia

For some time now, our research group has been involved in a series of investigations of the outcomes of treatment for benign prostatic hyperplasia or "BPH". The investigations are part of an effort to come to terms with the puzzling geographic variations in rates of use of medical care. We became convinced that a principle reason for the variations is differences in physician practice style and that a resolution of the variation puzzle required direct inquiry into the outcome significance of the various opinions or clinical theories underlying the varieties of practice style. By the early 1980's, Dr. Daniel Hanley, David Soule and Alice Russell had succeeded in organizing leading physicians in Maine into study groups to investigate the variations. These study groups became the focus for an alliance between practicing physicians and researchers that made many of our studies possible.

The assessments of alternative treatments for BPH have become the most widely known, and it is fair to say that it is in the groping for solutions to the problems encountered here that has advanced our understanding of outcomes research. The BPH study group, organized in 1982 by Dr. Robert Timothy, consists largely of practicing urologists. Our assessment team consists of an interdisciplinary group of clinical evaluative scientists including research urologists, medical care epidemiologists, decision

analysts, statisticians, psychometricians, computer scientists and experts in interactive video disc technology. I have listed the members of our team in an accompanying table.

The assessment team took on the issue of treatment of prostatism or obstruction of the urinary tract due to benign hyperplasia of the prostate gland or "BPH." BPH is a very common condition, affecting the majority of men by the time they reach the seventh or eighth decade of life.

The assessments described here have been published in the Journal of the American Medical Association and the New England Journal of Medicine.[2]

One common treatment for BPH is an operation, a prostatectomy. The use of prostatectomy shows striking variations among neighboring communities so that in some places about ten percent of men undergo this operation by age 85 while in other communities the proportion can be as high as fifty percent. Some 340,000 prostatectomies were performed for BPH in 1985 at a cost of about $4 billion.

Another common treatment for BPH is watchful waiting. In communities with low rates of prostatectomy, proportionately more men with BPH are treated by the strategy that prostatectomy is an elective procedure, reserved for those with truly bothersome symptoms.

When we began our study, the principle treatment for BPH involved either watchful waiting or prostatectomy. Our assessment began with a discussion between the researchers and the members of the physician study group (who represented many different geographic areas in Maine). The discussion focused on the geographic variations in prostatectomy with the objective of uncovering the different points of view or clinical theories that might be behind the variations. These discussions (and a review of the scientific papers published on BPH) uncovered **an important and unsettled controversy concerning the indications for the operation:**

> **Many physicians hold to the theory that prostatectomy should be performed early in the course of BPH as a preventive measure to increase life expectancy.** They reason that if the operation is delayed, the patient will be older and at higher risk when the operation finally becomes

2. Wennberg JE, Roos N, Sola L, Schori A, Jaffe R. Use of claims data systems to evaluate health care outcomes: mortality and reoperation following prostatectomy. JAMA 1987; 257(7):933-936. Barry MJ, Mulley AG, Fowler FJ, Wennberg JE. Watchful waiting vs immediate transurethral resection for symptomatic prostatism: the importance of patient preferences. JAMA 1988; 259(20):3010-3017. Fowler FJ, Wennberg JE, Timothy RP, Barry MJ, Mulley AG, Hanley D. Symptom status and quality of life following prostatectomy. JAMA 1988; 259(20):3018-3022. Wennberg JE, Mulley AG, Hanley D, Timothy RP, Folwer FJ, Roos NP, Barry MJ, McPherson K, Greenberg ER, Soule D, Bubolz TA, Fisher E, Malenka D. An assessment of prostatectomy for benign urinary tract obstruction: geographic variations and the evaluation of medical care outcomes. JAMA 1988; 259(20):3027-3030. Roos NP, Wennberg JE, Malenka DJ, Fisher ES, McPherson K, Folmer Andersen T, Cohen MM, Ramsey E. Mortality and reoperation after open and transurethral resection of the prostate for benign prostatic hyperplasia. N Engl J Med 1989;320:1120-1124.

unavoidable; if the operation is delayed, life expectancy is reduced. For most patients, according to this theory, watchful waiting is not a reasonable option.

Other physicians argue that the need for the operation is not inevitable and that watchful waiting is a reasonable option for patients who prefer to live with their symptoms in order to avoid the risk of operation. For most patients, according to this theory, prostatectomy does not improve life expectancy and that the primary reason for an operation is the relief of symptoms and improvement in the quality of life.

The assessment team tested this conflict in theory to reach several conclusions. Using evidence from the literature and from claims data, **the assessment demonstrated that the preventive theory was incorrect: an operation in patients with uncomplicated BPH--and most patients are like this--may even cause a slight decrease in life expectancy. The assessment thus confirmed the opinion of those physicians who felt the operation was justified on the basis of its value for reducing symptoms and improving the quality of life.** Interview studies with patients before and at three, six and twelve months after surgery documented symptom and functional status changes in relation to the operation, and showed that the value of the operation for most patients rests in its superior effect over watchful waiting in reducing symptoms and improving the quality of life. But these gains are available only to patients willing to take the risks of the operation which include death, failure to improve symptoms, impotence and incontinence. **The decision to undergo the operation is thus highly dependent on the patient's preferences for outcomes and attitudes toward risk.**

Note that this substantial clarification of theory occurred without the use of a prospective clinical trial. Our methods included the use of focus groups with physicians to learn about theory, and with patients to learn about expectations and the outcomes that mattered to them. The literature review and the claims data provided sufficient information to study the actuarial expectations for the operated and unoperated patient (without chronic retention) and test the preventive theory of early prostatectomy. We had to depend on the placebo arm of a few drug trials and a scant series of four studies of BPH patients treated with watchful waiting for estimates of the natural history of symptoms and the frequency of cross over to operation. We found no satisfactory information on symptom relief after surgery in the literature, so we conducted our own study. The results provide convincing evidence that the operation is much more effective than watchful waiting as a treatment for BPH symptoms. Thus, there is no dispute about the superiority of surgery over watchful waiting. Decision analysis, used to test the preventive theory, also demonstrates that the decision to undergo the operation is sensitive to patient values concerning the disutility of impotence, incontinence and to the operative mortality

rate. The subjective factors of risk aversion and degree of botheredness thus emerge as important elements of rational choice.

By clarifying controversies, establishing correct theory and providing detailed probability estimates for most relevant outcomes, some of which had not been previously studied, the assessment has immediate practical value for improving clinical decision making. The practice style related causes of variation in prostatectomy rates are traced to an incorrect belief in the preventive theory of early prostatectomy and failure to take patient preferences into account in recommending prostatectomy. The remedy for unwanted practice style variations, we conclude, requires the active engagement of the patient in the decision. It involves informing physicians and patients of the risks and benefits of prostatectomy and its alternative, watchful waiting, and actively engaging the patient in the decision process.

Our assessment team is developing new ways to make the detailed probability estimates we have in our database available to patients and physicians in "real time" so they may be used in clinical decision making: We have built a "BPH Shared Medical Decision-Making Procedure" based on interactive video-disc technology. This interactive program is designed to be administered in the physician's office after an initial data entry of standardized information on health status and physical condition. The patient is also asked to answer questions about his symptoms, functional status and the strength of his feelings about them to identify the relevant prognostic subgroup to which the patient belongs so the information presented to him is the best available estimate.

The patient is then presented with an audio-visual narration depicting the choices he faces, their various possible outcomes and associated probabilities. Interviews with two physicians who are BPH patients (one who chose watchful waiting and the other prostatectomy) convey to the patient that he indeed has a choice: if physicians choose differently so can their patients. Other interviews are testimonies about the principal outcomes, including an example of a complication associated with either choice. The interactive computer feature of the Shared Medical Decision-Making Procedure means that information on the probabilities for outcomes presented to the patient are specific to his subgroup, according to symptom severity and age. The patient can also exercise options to learn more about issues of particular concern as well as review what he has seen. At the end, he is given a printed synopsis of what he has seen to discuss with his family and physician. The physician then helps the patient make his decision.

Although the BPH vs. watchful waiting assessment we have conducted helps clarify controversies in basic clinical theory and provides better estimates

than previously available for symptom status, important uncertainties remain about some of the probabilities that are important for patients with BPH trying to evaluate risk. For operated patients, the sample on which the estimates are based is small (about 400 men), so the standard deviations are sometimes large. The situation for the untreated patients is even less satisfactory. We were unable to obtain an accurate estimate of the chance of a second episode of acute retention, given a choice of watchful waiting, which is important information for men who have already had one episode of acute retention. The characteristics of the watchful waiting subgroup at risk for progression to chronic obstruction (with the potential for bladder decompensation) is also unclear. The attributable post-operative (30 day) risk of death from prostatectomy remains unclear.

The interactive video disc program will help fill in these missing probability estimates because it is also a tool for outcomes research. At the time of initial viewing, the patient can be enrolled in a prospective study of outcomes based on his choice of treatment--a cohort study we call a preference trial. For outcomes research, the patient must return later (e.g., after 3, 6, or 24 months), regardless of his treatment choice when additional information about his health and satisfaction with his choice will be obtained and entered into the database. These data, accumulated over time and for many patients, can then be used by researchers to update the information presented to the patient. In this way, the device participates in its own update and helps improve the scientific basis of medicine. We also plan research protocols to help better understand the framing effects of our data displays and to learn more about how to help patients make decisions consistent with their own preferences. An important objective is to learn more about and improve the role of the physician as counselor and "cognitive" advisor to patients.

In the course of our work we have encountered a number of other theories or controversies concerning the treatment of BPH. One is an "old" theory that the transurethral approach to prostatectomy has better outcomes than the open prostatectomy. Another is that alpha-blockage drugs approved for the treatment of hypertension are useful treatments for BPH. We also found new techniques for treating BPH based on balloon dilation, identified two promising drugs now undergoing FDA evaluation, a less invasive operative technique (prostatotomy), and a treatment based on micro-wave diathermy which is thought to improve symptom status by reducing prostatic size through the scaring of tissue damaged by micro-wave. As our thinking about our role has evolved, we have come to see the advantages of extending the responsibility of the assessment team to include all alternative treatments, the old as well as the emerging. We therefore plan to address the evaluative challenges each of these theories presents. Much of this work is now in progress and we will be supported by the funding that is made possible by H.R. 1692.

A particularly important problem that remains to be settled is the relative effectiveness of two surgical approaches to the prostate--the TURP or the open prostatectomy. Over the past three

decades, transurethral prostatectomy became increasingly more popular until today it has virtually replaced the older open operative techniques. This replacement, occurring without the benefit of prospective clinical trials, reflects the belief that the TURP is a safer, less invasive operation that is effective in the long-term.

Since the administrative databases available to our team extend backward to the 1960s, we have compared the outcomes of these two operations over a considerable span of time. The results indicate that **the open operation may be more effective. Patients with an open operation have significantly lower rates for stricture and reoperation, suggesting that the more complete removal of the prostate following the open operation, less traumatizing to the urethra, results in better long-term reduction in urinary symptoms. More puzzling and disturbing is the unexplained elevation in risk of death in the years following TURP.** In separate studies undertaken in Maine, Manitoba, Oxford and Denmark, we found the risk of death to be significantly higher in the five years following a TURP. **The consistency of the findings and our failure to explain them on the basis of data available in medical charts led us to conclude that differences in patient illness or co-morbidity should not be assumed to be an adequate explanation for the increased mortality associated with TURP. We recommend a careful randomized prospective study to establish whether the finding is due to unmeasured patient differences or is an effect of treatment.**

Over the past several months, our assessment team has been in contact with a number of urologists in various countries, including the leadership of the American Urological Association (AUA). **We are extremely pleased that the leadership of the AUA has accepted our recommendation and is urging its members to participate in a large-scale clinical trial. We are now meeting with the AUA and urologists from other countries to plan this trial.**

Establishing the Evaluative Clinical Sciences and the Mandate For Outcomes Research

It is increasingly apparent that the large investment in biomedical science has not resulted in a consensus among physicians on the correct way to practice medicine nor has it resulted in an orderly assessment of theory. Quite the contrary, biomedical science, by virtue of its prodigious success, appears to have increased uncertainty and practice style variation by offering an ever increasing supply of new technology and new biomedical ideas. This explains the shocking variations in costs and utilization among Boston and New Haven where the scientific credentials of the medical communities are state-of-the-art.

The emergence of the evaluative clinical sciences and outcomes research is a response to the intellectual crisis created by the growing awareness of inadequacies in the scientific basis for

clinical decision making. The solution the evaluative clinical sciences seek to make possible is better clinical decisions based on fuller understanding of outcome probabilities and active participation of patients in selecting the treatments they want.

The nature of the assessment problems the evaluative clinical sciences seek to address and the way innovation occurs in most fields of medicine suggest certain principles to extend the systematic assessment of outcomes to include FDA approved drugs used by physicians for non-approved indications, surgery, diagnostic tests and the uses made of hospitals:

1. Assessments must be conducted according to the principles of "regular science" as part of the nation's system of peer reviewed medical research.

2. Assessments must be ongoing: the nature of innovation in medicine requires continuous evaluation and reevaluation as new theories arise.

3. Priorities must be set: the assessments done first must be those that matter most.

4. Regulation will not work: innovation for most medical treatments is decentralized and assessments not easily mandated through formal regulation.

5. Rapid completion is essential: assessments must produce useful results within a reasonable period.

These principles are reflected in the design and philosophy of The National Center for Health Service Research's Patient Outcome Assessment Research Program, a program which will benefit from the increase in funding for outcomes research made possible by H.R. 1692:

1. **Regular Science.** The uncertainties we are talking about are fundamentally scientific uncertainties that can only be resolved by obtaining information and using it to test theory. The needed improvements in the scientific basis of clinical decision making depend on these assessments and they must proceed in an orderly fashion to develop a body of knowledge based on proven rules of evidence and formally structured peer review. The intellectual rigor now commonplace in the biomedical sciences must be the standard. **In the final analysis, the authority and effectiveness of the assessments depend on their credibility as objective science. The principle of scientific independence assures a balanced, unbiased source of information about what is known and what remains controversial in the evolution of clinical theory.** The National Center, as part of the federal government's scientific establishment, offers these assurances.

2. **Continuity and Continuing Responsibility.** Innovation in medicine is dynamic and the need for assessments is an iterative, ongoing one. Information needs continuous updating and improvement; new assessments will be needed as new theories develop and old ones evolve. The BPH assessment team uncovered several new treatment theories which need assessment. We found a new approach to BPH based on the use of microwaves to shrink the prostate; a new, less invasive, operative approach based on a simple incision of the gland, and a new idea that BPH can be treated with a balloon that is expanded to push the prostate tissue aside. We also learned about drugs which may work. These theories need testing. **The National Center's Outcome Assessment Program establishes assessment teams with ongoing responsibility to keep abreast of new developments and to perform (or bring others to perform) adequate studies. Their recommendation on the need for randomized clinical trials offers further guidance to the rational evaluation of medical theory. Like their counterparts in biomedical medicine, the scientists involved need to make career investments in a problem area. The experience and knowledge are cumulative. Assessment projects dealing with major human illnesses such as BPH need to be continued indefinitely.**

3. **Priorities are Needed**. The assessment projects that are established first should be those that matter most to patients and to those who are concerned with the quality of care and the allocation of scarce resources. Most would agree that **the focus needs to be on testing the alternative ways of dealing with common medical problems for which at least one treatment option is known to be costly and/or risky. I have listed my priority conditions in an accompanying table.** Even though my list is small, it covers the large majority of costly variations in surgery and hospitalization.

4. **Regulation Will Not Work**. The mandate to extend evaluations to approved drugs used in novel ways, the use of surgery, diagnostic tests, and hospitals cannot be accomplished through regulation. There is an essential difference between the research and development strategies of the drug industry and the dynamics of innovation for most medical practices. Drugs follow a linear process of technology development and assessment, from the bench to the animal laboratory and finally to human experimentation. The mandate to evaluate is easily accomplished through regulation tied to the license to market, and the resources needed for evaluation are provided as part of corporate policy. **Most medical innovations develop as part of the problem solving activity of physicians in their daily encounters with patients, in decentralized environments where there are few resources available for evaluation. Assessment teams are an alternative to regulation in a situation where regulation is not likely to succeed.** They accomplish their mandate for evaluation because team members are drawn to the intellectual, scientific and ethical questions of efficacy, because their professional careers are vested in the evaluative sciences and because The National Center provides the resources needed to make the evaluations happen.

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5. **Rapid Completion is Essential**. The principle, "quick is beautiful" I borrow from Freeman Dyson who notes that projects that are timely and offer results in a few years succeed, while those with longer time frames tend to fail. The assessments The National Center will undertake fit this principle well. The utility of outcomes research studies does not depend on the randomized clinical trials they may generate. **As the prostatectomy assessment illustrates, substantial clarification of clinical theory is possible on the basis of non-experimental studies alone. The Congress, by investing in The National Center's Outcome Assessment Program, can expect substantial results within two to three years.**

The Response of the Profession to Outcomes Research

The Congress can expect cooperation from the medical profession as it implements a program of outcomes research. **The assessments of health care outcomes will challenge the theories and practice patterns of the nation's physicians, but the challenge will be on the high ground of scientific evidence and an imperative all physicians recognize–the need to do what is best for patients. All physicians share the burden of uncertainty. They have been forced to act on behalf of their patients, using the theory and information they have and with little help from the evaluative sciences. More than anyone, they want to know what is best for patients.** The actions of physicians working in Maine's Medical Assessment Program and the leadership of the American Urological Association exemplify the constructive response practicing physicians make to the challenge to assess medical practice. The leadership among the American Medical Association, the societies representing the nation's medical specialties and the Joint Commission on the Accreditation of Healthcare Organizations understand this need, and they are moving to promote professional responsibility for assessment of practice patterns. **The strengthening of evaluative clinicial sciences in the nation's academic medical centers and medical schools will be a very important product of the increased funding made possible by this legislation.** Career opportunities will develop; new perspectives on the need and approaches for evaluation and the practice of cost-effective care will be brought to the education of physicians. The increased funding for outcomes research made possible by H.R. 1692 will galvanize the will to undertake the evaluations necessary to improve the scientific basis of clinical decision making.

Suggested Priority Conditions or Illnesses for The Medical Care Quality Research and Improvement Act of 1989 (S1692)

Condition	Treatment Controversies
Stable Angina	Bypass Surgery vs Angioplasty vs Drugs
Unstable Angina	Bypass Surgery vs Angioplasty vs Drugs
Arteriosclerosis	Endarterectomy vs Drugs; Causing Stroke
Peripheral Vascular Disease	Bypass Surgery vs Angioplasty vs Medical Management
Lens Extraction	(by type of surgery) vs Watchful Waiting
Gallstones Management	Surgery vs Stone Crushing vs Medical vs Watchful Waiting
Arthritis of the Hip and Knee	Surgery (by type) vs Medical Management
Non-Cancerous Conditions of the Uterus	Surgery (by type) vs Hormone Treatment vs Watchful Waiting
Prostatism	Surgery (by type) vs balloon dilation vs drugs vs watchful waiting
Ear, Nose & Throat Conditions	Surgery by type vs various drugs
Herniated Disc	Surgery vs various medical treatments
Acute and Chronic Medical Conditions:	
Back Pain/Strain Gastroenteritis	Hospitalization vs ambulatory-based care;
Respiratory Disease Heart Disease	ICU vs Usual Ward Care

Chairman STARK. Dr. Ellwood.

STATEMENT OF PAUL M. ELLWOOD, JR., M.D., CHAIRMAN, INTERSTUDY/QUALITY QUEST, INC., EXCELSIOR, MN

Dr. ELLWOOD. I want to take this opportunity to express support for H.R. 1692, Mr. Chairman. I will summarize my statement, which I have supplied for the record.

This bill addresses some areas of concern that have become particularly evident with the restructuring of the U.S. health industry. We have learned from the restructuring that changing the organization and incentives of the health system is not enough. I am also persuaded that resolving questions of clinical effectiveness, independent of the site of care, will not completely resolve these problems of cost, effectiveness, and provider quality.

To allow our complex health system to function rationally, a universally applied tool is needed to measure, manage, and account for the impact of medical care on clinical status and the quality of people's lives. Such a tool is a natural outgrowth of H.R. 1692 in health services research, and I believe it should be included as a critical component of everyday medical care. We should not treat this as strictly a research problem.

I call this class of management tool "outcomes management." Outcomes management has to be based on good science. Outcomes management systems would measure and follow patient's functional status and quality of life over time, using terms that are readily understandable by policymakers, patients, payers, and providers. We would document the changes in the patient's clinical status as a result of therapeutic interventions. We would have to ensure that this data is collected in such a way that it can be pooled so that organizations and treatment methods can be compared.

By taking this universal approach to outcomes research or management, we can not only learn what works in medical care, but we can learn where it works. As organizations progressively take over the delivery of health care, understanding how they affect people's health is essential to improving the management of these medical care organizations. Of course, knowing precisely who gets good results is vital to patients and payers as they make decisions regarding where they will get their care.

Quality Quest, a nonprofit affiliate of InterStudy, has spent the last 10 months in a cooperative research and development effort sponsored by InterStudy, the Kaiser Family Foundation, and HCFA. This work has gone very well and has established the feasibility of developing a practical outcomes management system.

Our intention is to put this system in the public domain. I agree with Dr. Brook that these things should be openly and publicly available. We have been simply playing the role of a catalyst and organizer trying to facilitate the interaction of organizations like the joint commission, which is outcomes oriented, various researchers, and the Government in developing this system. Efforts are underway to establish outcomes management in a variety of user settings for about 15 clinical conditions.

As an indication of how well things are going, I have found this idea is moving much faster than the HMO-managed care idea. The

health system is more readily adopting the outcomes management concept. We have learned in less than a year that what started out as an idea to be implemented over many years has suddenly become a large-scale movement.

Over 100 health care organizations have stated their intent to help with the design and implementation of outcomes management. They do not consider a more sophisticated assessment of health services to be experimental. They are prepared to install a uniform data base, and to modify it as they gain more experience. They are willing to put their present experience to use and be accountable for the impact of health care on quality of life.

Second, we have learned that measuring the effects of medical treatment on patients is a costly undertaking. But these organizations regard this as a basic tool. They are willing to pay their own way in installing and using outcomes management as a routine part of medical practice. Many early users are willing to make their data available to separately funded researchers pursuing more detailed studies of specific conditions or medical practices.

H.R. 1692 funds will be required to expand and perfect the elements of an outcomes management system, such as a uniform data set. I think that we have to move toward some sort of a national health data center that can serve as a repository for health outcomes information from all over the country. Obviously, as the bill implies, more funds are going to be necessary for training users.

Therefore, I conclude that H.R. 1692 appears to be perfectly timed to tap into and support development efforts that are going on all across the country. H.R. 1692 can help bring those interests together in developing a practical, useful outcomes management tool which will be applied in hospitals, doctors' offices, and insurance companies all across the country.

[The statement of Dr. Ellwood follows:]

STATEMENT FOR THE RECORD
SUBMITTED BY PAUL M. ELLWOOD, JR., M.D.
Chairman of InterStudy/Quality Quest, Inc.
to the
HOUSE WAYS AND MEANS COMMITTEE
SUBCOMMITTEE ON HEALTH
on May 23, 1989

I wish to take this opportunity to express support for H.R. 1692 to amend Title XI of the Social Security Act, providing funding for research and education regarding the outcomes, effectiveness, and appropriateness of medical treatments funded through the Medicare program and others.

I. INTRODUCTION - AREAS OF CONCERN

H.R. 1692 addresses areas of concern that have become particularly evident with the restructuring of the U.S. health industry which began in the early 1970's. Movement toward a system influenced by market forces and "managed care" mechanisms has led patients, payers, and managers of health care organizations to seek increased influence over medical practice. However, for the health market to work efficiently, purchasers must have understandable information about what "health improvement" they are buying to appraise its true value. At present, the newly empowered purchasers of health care do not have the information necessary to make rational decisions.

This inability to measure and understand the effect of patient, payer and provider choices on a patient's well-being results in uninformed patients, skeptical payers, frustrated physicians and besieged health care executives. Patients commonly judge their medical care on the quality of service (physician manner, waiting time, etc.). Payers are perplexed by repeated demonstrations of wide variations in practice styles between settings with no corresponding difference in health outcomes. Physicians believe financial concerns are jeopardizing patient care. Executives are caught without management tools to evaluate health outcomes balanced against resources consumed ... only the price of medical care is systematically measured. Given this focus upon financial outcomes, pressure is building to simply cap expenditures without regard to effectiveness or value.

II. WHAT IS NEEDED

To allow our complex health services system to function rationally, a tool is needed to measure, manage, and account for the effects of medical services and other factors on a patient's health status. Such a system (a natural outgrowth of outcomes research and educational activities envisioned by H.R. 1692) should be included as a routine component of ordinary medical care. This system must:

- measure a patient's functional status (quality-of-life) over time, using terms readily understandable by (and relevant to) the patient, payers and providers;
- document changes over time in a patient's clinical condition as a result of therapeutic interventions;
- insure that data are collected in a common format using common protocols across a large number of sites;
- maintain data collected from multiple sites in a single repository, allowing evaluation of patient experience across sites, therapeutic regimens, providers, etc.;

Health services documented in this fashion will constitute a massive longitudinal series describing changes in patient condition and associated treatments, essentially being an ongoing clinical trial. Large numbers of cases within given conditions (subject to various therapies) are required for statistically valid conclusions to be drawn. Very few organizations can accumulate such a number of cases within their own experience, thus government leadership and collaboration with private health organizations is essential in establishing uniform data protocols and data pooling.

Once established, this system would be used by providers to:

- assess and choose therapies;
- estimate resources to be expended in treating a condition;
- follow the natural progression of health conditions; and
- establish standards of treatment for specific conditions based on health outcome performance.

Purchasers, patient groups and policy makers would use the system to:

- predict the cost of care;
- select among sources of care;
- design health insurance benefits; and
- establish standardized and valid methods of accounting for health care organizations' effects on health/quality of life.

This approach embodies three concepts:

1. Patients' health-related "quality of life", along with more traditional clinical results, are an appropriate frame of reference for measuring the quality of health services, in

contrast with the present emphasis upon provider reputation, physician training, number of visits, hospital days, laboratory test volumes, and expenditures.

2. Medical care is increasingly practiced by organizations. These organizations will be explicitly and publicly accountable for the effects they have on patients' health;

3. The management of health care organizations is a clinical science. Health care organizations will have physician executives equipped to understand and manage organizations' effects on patients' health; and

This represents a change in the "paradigm" of health care services. None of these concepts are generally applied within U.S. health care organizations.

III. EXPERIENCE WITH BUILDING AN OUTCOMES MANAGEMENT SYSTEM

Quality Quest (a non-profit affiliate of InterStudy) has spent the past ten months in a cooperative research and development effort sponsored by InterStudy, the Kaiser Family Foundation and HCFA. This work has established the feasibility of developing a practical outcomes management system. Our intention is to pursue development of such a system, placing it within the public domain. Quality Quest is playing the role of catalyst and organizer, facilitating the development of component technologies by leading researchers, clinicians, professional organizations and government agencies. Efforts are underway to install the developing system in a variety of user settings, establishing the practicality and utility of survey instruments and data collection protocols proposed for measurement of patient outcomes.

The Outcomes Management System (OMS) being fostered by Quality Quest will include various components. These include:

- "generic" survey instruments and protocols for the collection of data describing patients' functional status, demographic characteristics, insurance company, treatment setting, and satisfaction with services provided (functional status information will be collected both before and after treatment for all patients regardless of presenting condition);

- condition-specific functional status and clinical data collection instruments and protocols also to be used in describing changes in patient condition over the course of treatment;

- a "national repository" for the pooling of data from all providers, charged with maintaining the integrity of the database and facilitating appropriate use; and

- a cadre of physicians and other health outcomes managers (trained in

epidemiology, computer science, and health services research, as well as medicine) working in provider and payer organizations. They will work to analyze and interpret OMS data, recommending policy changes within their organizations and/or informing their colleagues about alternative practice patterns and their implications.

Twenty conditions have been identified as "targets" for early inclusion within the OMS.

1. Cerebrovascular Disease
* 2. Diabetes (Byron Hoogwerf, M.D. - Cleveland Clinic)
* 3. Prostatism (Floyd Fowler, Ph.D. - Univ. of Mass.)
4. Angina
* 5. Hip Fracture (John Fitzgerald, M.D., Ph.D. - Ind. U.)
6. Arthritis (including candidates for hip and knee replacements)
* 7. Cataracts (Jonathan Javitt, M.D., MPH - Johns Hopkins)
* 8. Depression (Kenneth Wells, Ph.D.- RAND Corp.) (tentative)
9. Alcoholism
10. Cholelithiasis
* 11. Low Back Pain/Strain (Richard Deyo, M.D., Ph.D. - VA)
* 12. Hypertension (Richard Grimm, Jr., M.D., Ph.D. - U. Minn.)
13. Gastritis/Esophagitis
14. Caesarean Section Delivery
15. Hysterectomy
16. Prematurity
17. Chronic Obstructive Pulmonary Disease
18. Retinal Detachment
19. Glaucoma
20. Peripheral Vascular Disease

* = specification under development

The OMS will track the effects of ordinary medical care, and fit into existing or evolving computerized medical record, claims processing, or hospital information systems. In combination with relevant financial records, it is meant to be a permanent database capable of isolating the experience of individual patients (or aggregations of patients) by diagnosis, treatment, provider group, etc. The result will be a powerful tool for management of clinical services, comparable in significance to existing financial management systems.

IV. WHAT WE HAVE LEARNED

1. What started out as concept to be implemented over many years has suddenly become a large-scale movement. Over 100 health care organizations have stated their intent to help with the design and implementation of a prototype Outcomes Management System in cooperation with Quality Quest. They do not consider a more sophisticated assessment of health services to be experimental ... they accept the implicit paradigm shift, and are

prepared to install the OMS and modify it as experience is gained.

2. Measuring patient outcomes (the effects of medical treatment on patients) will be a costly undertaking. As basic tools are developed, there are many groups willing to "pay their own way" in installing and using outcomes management tools as a routine part of medical practice. Many of these groups are willing to make their data available to separately funded researchers pursuing more detailed studies of specific conditions or medical practice patterns.

3. Funds from H.R. 1692 will be required to expand and perfect components of the "uniform data set" required for effective outcomes management, and to plan and establish a central depository for uniform health data. I believe it realistic to expect planning and establishment of a "National Health Data Center" to be accomplished over a two year period, with accumulation of uniform data from various sites proceeding from that point.

4. Effort must be devoted to training users (physician managers, payers, employers, and patients) to take full advantage of outcomes data as it becomes available. The concept of using outcomes data in practicing medicine is accepted ... education regarding specific techniques is required.

V. CONCLUSION

H.R. 1692 appears to be perfectly timed to tap into and support development efforts across the country, bringing those interests together in a practical, useful outcomes management tool. Based on our early experience in applying the lessons of outcomes research to the United States health system, we suggest broadening the definition of supported activities in Section 1140 (d)(A), adding "... or uniform data protocols ..." after the word "guidelines".

Passage of H.R. 1692 can improve our knowledge of the effectiveness of medical care. We can now go beyond limited research activities and incorporate outcomes assessment activities into the everyday practice of medicine.

Chairman STARK. That is just what they said last year when Mr. Gradison wrote the catastrophic bill. [Laughter.]

At that point, I will recognize Mr. Gradison to inquire.

Mr. GRADISON. On that point, I would rather quit while I am ahead.

I do thank the panel, not only for their testimony today, but for the leadership which each of the members of this panel has shown over the years in working in this field. I am very excited to see some of the progress that has already been made, and just hope that the initiative that we are considering will permit us to move more broadly and more quickly into fields which have not yet been examined as carefully.

I have no questions. Thank you, Mr. Chairman.

Chairman STARK. I am sorry that I was called away from the podium during your testimony, and I have been glancing at some of it. Dr. Ellwood, one of the problems that we have had on this committee is not being professionally trained and constantly concerned with trying to save money or spend what money we have efficiently. We really do not know what we are buying. We cannot spell the procedures or pronounce them, or if we can pronounce them, we do not know where they fit. I mean, we are really, I suppose, just like most patients. We just really do not know.

Will this type of research, do you think, eventually lead to a more empirical system whereby we could purchase services more efficiently with our comfort level going up so that we are not interfering in the practice, but that we could say, look, we are paying for too many X procedures in this group of elderly or not enough Y's, and that ought to be a more efficient way? Or is this strictly going to be something that is going to be used in the art of medicine to help it along?

Dr. ELLWOOD. I think this research is going to be essential to establishing value, especially if we choose to measure value on the basis of impact on quality of life. Putting the information in the vernacular so we can all understand will, I think, help patients to make better decisions; it will help you to make better decisions.

Incidentally, your problem is not unique. I just returned from a trip to Europe and met with officials in health care in Britain and Spain. They were saying the very same things: "What are we getting for our money? How can we contain these rising costs without understanding what impact health care is having on the quality of people's lives?"

Chairman STARK. One thing the Canadians suggested to us about our system here and what they feel is lacking—the only thing, actually, that they feel is lacking in their system is that they are not doing outcomes research. And they do not seem to have the motivation. They envy us that we have that in our system.

Do we have any information now in some areas of medicine—and I think I am directing this primarily at Dr. Wennberg—where data has already been gathered through the PRO system or others, where we could start with certain limited numbers of procedures, making some judgments already as to—I am thinking of the TURP procedure as opposed to—I guess you would call it open surgery techniques. In limited areas, do we have some information that we could start to put to work that would be useful for us now?

Dr. WENNBERG. I am much more optimistic than Secretary Sullivan is on the timeframe for this. We have been working now for less than 4 years intensively with physicians in Maine, with an interdisciplinary research group, systematically going through the different reasons people have for treating BPH, benign prostatic hyperplasia. I think that accounts for some 10 percent of the cost to the Medicare Program in terms of outlays. It is about that much.

Before we started, no one had been interested in the systematic testing of these treatments. The FDA was interested in drugs, so they were comparing drugs for treating BPH to placebos. But no one was concerned with comparing a drug to an operation, to a balloon dilation, to diathermy, all these new techniques.

We took the regional variations issue as our point of departure and said: Can we solve the problem of variations? Can we find out why they occur? And at this point in time, I think we can say quite clearly that we know why they occurred. They occurred because of differences in belief structures and theories of practice on the part of physicians.

Moreover, we were able to test those theories and to conclude that one major idea—namely, that you operate early to make people live longer—was wrong. It just did not hold water, so to speak.

So, basically, that meant that the operation was done for quality of life. By getting the information on all the outcomes that matter—symptom reductions, incontinence and so forth—we are now in a position to inform patients and physicians about the outcomes for various subgroups. It is the information that is injected back into the system from that assessment which is already beginning to change practice patterns.

So I believe that these assessment teams that I have been talking about can produce in a much shorter timeframe than many suppose. They are holistic in the sense they are interested in all alternative treatment theories. And the terms ought to exist on an ongoing basis to provide the kind of information we need.

Chairman STARK. Good news. Thank you very much.

Mrs. Johnson.

Mrs. JOHNSON. Thank you, Mr. Chairman.

Dr. Ellwood, you made an interesting comment in the course of your testimony that I would like to ask you to enlarge on. You said that this approach is being very well accepted by the medical community and is being better accepted than managed care.

Dr. ELLWOOD. Well, I have been involved with the introduction of both concepts, and I would stand by my assertion.

Mrs. JOHNSON. Could you enlarge a little bit on why and what the impact is going to be? Are patterns of practice guidelines going to achieve the goals that we have been looking to achieve through managed care? Will they do it with less administrative overhead? Will they do it with more preservation of individual initiative in medical treatment?

Dr. ELLWOOD. Outcomes management technology is essential to managing care, which means being more selective about providers, procedures, and how to pay for good results.

As to the acceptability of such a system, even though I think in many ways this involves a major shift in the medical paradigm, there is growing recognition among physicians and purchasers that we really do not understand fully what we are doing, and this ignorance is a very serious problem. There is recognition that we do not follow our patients well enough. People are just searching for some common, objective way to organize themselves around a uniform method of tracking patients so that they can understand more readily what value, in human terms, is coming from our huge investment in health care.

I think that is why it is reaching such a wide audience so quickly.

Mrs. JOHNSON. And do you think guidelines have the potential to achieve the goals that we have sought to achieve through setting up new institutions without necessarily relying on those institutions?

Dr. ELLWOOD. Yes, I do. I think that the managed care idea ran into two problems. One was this problem that we are talking about here today: That it does not do any good to change doctors' incentives if you do not know the proper treatment for a patient to get an ideal result.

The second problem we ran into was a problem of consumer expectations. They seemed to believe that more medical care is better; therefore, any effort to reduce the quantity of care that people got was perceived as an effort to reduce the quality of care. By making more obvious what effects medical care has on people, plus and minus, in a way that all can understand, I think we can get around this idea that a superabundance of medical care is the way to eternal life.

Mrs. JOHNSON. Thank you. Very, very interesting comment. I appreciate it.

Chairman STARK. Mr. Anthony.

Mr. ANTHONY. Thank you, Mr. Chairman.

Awhile ago, I asked Dr. Sullivan a question, and I must admit that I was throwing a dart in the dark. I had no earthly idea that things were as chaotic over there as he just indicated. Since he has testified, I have gone back and reviewed the situation with the staff, though, to find out exactly what the circumstances are over there. I must profess that I am extremely disturbed at the slowness with which they have placed people in very key and sensitive places. I was also disturbed about the time factor. You mentioned that you disagree with the time factor.

Again, I am concerned about this from a cost standpoint; and from reading the report from Mr. Brook, while there is a lot of good information in here that says we are on the right track and we ought to go forward and we ought to expand this to a lot of other procedures and we need to educate a lot of people—and it looks like you have provided us with a great deal of ammunition to go the next step—if we do not have the people in place, though, we cannot logically go to the next step.

Could you help me with two questions? One, is it hurting your efforts on the outside because of the great number of vacancies in very key and sensitive positions? And, two, could you more clearly talk about this time factor in terms of where you think this sub-

committee could go and what the next logical extension would be to try to gather the data and better understand where we are?

I will just direct it to all three of you, and any one of you can answer.

Dr. BROOK. I think what we have to do is simultaneously begin on the process of producing better data such as Jack described with the prostate example, and simultaneously applying that data. I will just spend some time on the latter for a second.

Luckily, when you look at how Medicare money is spent, and if you use that as one way of targeting where to go next, there is a very skewed distribution. There are thousands of procedures we do as physicians to people, but a very small percentage of them account for a very large percentage of the resources.

It is absolutely, perfectly feasible to move tomorrow on the process of developing guidelines, standards, and appropriateness criteria for at least 15 to 25 procedures and have them done and in a usable form within a 2- to 3-year time period, if not sooner.

Doing this also requires research on making sure that the way one measures appropriateness is valid and reliable, because this is a new field. So it requires not only the simultaneous process of moving forward the agenda on trying to find out what works, but also how one combines information in a manner that produces valid conclusions. It requires all of those things being done.

Now, how should this be done? One way of doing this is to do it all internally in the Government, and that would require, I suspect, a level of staffing and commitment in the Government that may not be there at this moment, but could be there. The other option is to do it through some sort of a private mechanism.

We have been working with organizations such as the medical societies, the AMA, academic consortiums, academic health centers, to try to form consortiums of people that basically would be ready to go when the money was there to make it happen. At the moment, the rate-limiting step is the funds. And if the funds were available, we could generalize the results that have been done very quickly.

Mr. WENNBERG. I'd like to mention that. The National Center of Health Services Research has set up a program on patient outcomes research to establish assessment teams, like the one I described for prostatism, for the other major conditions that are associated with Medicare's big cost items, like cataracts, like the treatment of stable angina which involves bypass surgery, drugs, and angioplasty.

And this program is already underway. It needs the funds that will come from this legislation. As I remember, they have some 15 proposals which they are now reviewing, which will cover well over half of the items which are on the most costly items list for Medicare spending.

And this program will provide the basic scientific information needed for appropriateness guidelines and also for patient education.

Mr. ANTHONY. Mr. Chairman, I just have one final question, and I could just submit this in a letter form for the record if need be.

But I am always interested in a geographical breakdown between the urban areas and the rural areas. I come from Arkansas. So, if

any of your data has anything that would be useful for me in terms of any regional imbalances between big States and little States, or rural and urban areas, I would appreciate it.

Thank you.

Chairman STARK. Thank you.

I want to thank the panel very much for their contribution.

It is the Chair's intention to recess until approximately 11:15 a.m., at which point we would call the second panel to the witness table.

And so we will stand in recess until 11:15 a.m.

[Recess.]

Chairman STARK. The next panel I would like to welcome comprises Dr. Robert McAfee of the American Medical Association; Prof. Uwe Reinhardt from Princeton University, Woodrow Wilson School of Public and International Affairs; and Dr. Heather Palmer, who is chairperson of the American Medical Review Research Center, and the associate dean at the Harvard School of Public Health, representing the American Medical Peer Review Association.

Welcome, all of you, to the panel. As you testify, you may wish to identify for the record those accompanying you. Your prepared statements will appear in the record in their entirety, and please, leading off with Dr. McAfee, will you summarize or expand on your testimony in any way you're comfortable.

STATEMENT OF ROBERT E. McAFEE, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, AND GENERAL SURGEON, PORTLAND, ME, ACCOMPANIED BY JOHN T. CELLY, E.D., DIRECTOR OF OFFICE OF QUALITY ASSURANCE, AND TOM WOLFF, DEPARTMENT OF FEDERAL LEGISLATION

Dr. MCAFEE. Thank you very much, Mr. Chairman, and members of the committee.

My name is Robert E. McAfee, M.D. I am a physician in the practice of general and vascular surgery in Portland, ME. I am also a member of the board of trustees of the American Medical Association. Accompanying me today, Mr. Chairman, are John T. Kelly, M.D., the director of the AMA's Office of Quality Assurance; and Tom Wolff from the AMA's Department of Federal Legislation.

The AMA is very pleased to testify concerning H.R. 1692, the Medical Care Quality Research and Improvement Act of 1989.

Mr. Chairman, let me state at the outset in the very strongest terms, that physicians indeed want to provide the best care for their patients. Therefore, the AMA strongly supports outcomes assessment research and the private sector development, dissemination, and implementation of clinically relevant practice parameters to assist physicians in the diagnosis and treatment of specific diseases or conditions.

Practice parameters are not like a cookbook which provides only a specified course of action. Instead, parameters outline the range of appropriate tests and procedures for a given clinical situation. Even with parameters, physicians must remain responsible for tailoring treatment to what is most appropriate for the individual patient.

The primary purpose of practice parameters is to improve the quality of patient care by helping physicians and patients identify appropriate treatment options. Previous activities in this area, including the Main Medical Assessment Project, of which I have been privileged and delighted to have been a founding and participating member for the past 10 years, have shown that when provided with clinically relevant, well-documented scientific information concerning how to better treat patients, physicians will modify their practice patterns to optimize care.

An additional benefit of practice parameters may be to control rising health care costs by reducing the provision of inappropriate or marginally beneficial care.

Now, as the foundation organization for all of medicine, the American Medical Association is working with the medical specialty societies to facilitate their efforts to develop practice parameters as well.

Mr. Chairman, the AMA supports the intent of H.R. 1692 and the thrust of the section of the bill that provides for outcomes, effectiveness, and appropriateness research. We also support the development of standards for use in the collection and maintenance of research information, the dissemination of research findings, and the education of physicians and other providers in applying that research.

We are concerned, however, over the provision in the bill that would require the Secretary of HHS to develop practice guidelines. We think this provision should be modified. We believe strongly that the Federal Government and other third-party payors should not play a dominant role in the development of practice guidelines. Practice guidelines developed by the Federal Government would not be accepted by physicians who might be suspicious that cost savings, rather than quality, would be the Government's overriding consideration.

Moreover, the Government lacks the expertise necessary to develop clinically relevant and scientifically sound guidelines. Instead, the Federal Government should oversee the development of guidelines by providing grants or contracts to physician organizations, such as the AMA, which would then actually develop the guidelines.

We also believe that it is premature to plan to use the guidelines to make payment denials. The use of guidelines for payment denial and screening purposes should proceed cautiously and only with the advice of the medical profession.

Mr. Chairman, our statement includes a number of other recommendations for improving H.R. 1692. We urge you to give our suggestions careful consideration.

In conclusion, Mr. Chairman, the AMA strongly supports the private sector development, dissemination, and implementation of clinically relevant practice parameters. Practice parameters should enhance the quality of patient care by helping physicians and patients identify appropriate treatment options.

Practice parameters will also be more effective than arbitrary expenditure targets in assuring appropriate utilization. We believe that the medical profession in general, and practicing physicians in particular, should play a leading role in the development of prac-

tice parameters. We are hopeful that the Federal Government will provide financial support for projects in the private sector to develop such parameters.

Finally, while we support the intent of H.R. 1692, and a number of the provisions of the bill, we urge that the bill be modified as we have noted.

Mr. Chairman, we commend you and Representative Gradison for your interest in this important issue. I will be happy to answer any questions members of the committee may have.

[The statement of Dr. McAfee follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health
Committee on Ways and Means
United States House of Representatives

Presented by

Robert E. McAfee, M.D.
John T. Kelly, M.D., Ph.D.

Re: H.R. 1692, the "Medical Care Quality Research and Improvement Act of 1989"

May 24, 1989

Mr. Chairman and Members of the Committee:

My name is Robert E. McAfee, M.D. I am a physician in the practice of general surgery in Portland, Maine and I am also a member of the Board of Trustees of the American Medical Association. Accompanying me are John T. Kelly, M.D., Director of the AMA's Office of Quality Assurance, and Tom Wolff of the AMA's Department of Federal Legislation. The AMA is pleased to testify concerning H.R. 1692, the "Medical Care Quality Research and Improvement Act of 1989."

Introduction

The AMA has a long history of involvement and leadership in a wide array of activities to assure the quality of medical care for all Americans. These activities include accreditation of medical education programs (undergraduate, graduate and continuing), physician credentialing, technology assessment, and dissemination of peer reviewed scientific information through its many publications such as the Journal of the American Medical Association and nine medical specialty journals.

Recently, the AMA has undertaken a number of additional activities to improve the quality of medical care. These activities include the establishment of an Office of Quality Assurance and the development of guidelines for the establishment of quality assessment and quality assurance systems.

Outcomes Assessment Research

Over the past few years, a number of studies have identified unexplained variations in the utilization of health services; some studies have fostered the perception that some medical care may be inappropriate or marginally beneficial. We believe that the generalizations that have been made based on these studies are unjustified. In our opinion, there is inadequate information for statements that 10%, 15% or more of American medical care is inappropriate. Part of the concerns that have been identified may be a reflection of the rapidly advancing state of medical knowledge. To remain abreast of current clinical knowledge, physicians must digest an enormous amount of information from the scientific literature, conferences, colleagues, and personal experience. Physicians must analyze these various sources of information to determine their validity and relevance to their practice.

The AMA strongly supports outcomes assessment research that will provide a better scientific basis for clinical management decisions. Well-conducted outcomes assessment research could likewise improve both treatment decisions and quality assurance programs. While supporting such research, the research data currently available do not include or inadequately describe the many issues necessary to evaluate a patient's clinical condition (for example, degree of illness, accompanying medical conditions, individual preferences) and the many factors essential to evaluate treatment results (for example, control of symptoms, management of disabilities and quality of life). We are also concerned that, without appropriate safeguards, inappropriate conclusions may be drawn and ill-advised policy decisions may be made based on the results of outcomes assessment research. The complex issues involved in providing medical care to individual patients often cannot be reduced to algorithms and mathematical formulas. For example, based on the results of an outcome assessment study, a third-party payor could decide to eliminate reimbursement for a particular procedure because the treatment appears to be associated with a greater risk of morbidity and mortality than other treatment modalities. However, the study may be flawed because it failed to adjust properly for patient characteristics or other important variables. In addition, the procedure with the higher morbidity and mortality risk may be the most appropriate treatment for certain patients if, along with the greater risks, there are greater potential health benefits or if other procedures prove to be ineffective for the particular patient.

To help ensure that outcomes assessment research is clinically relevant and that the results of an outcomes assessment study are interpreted properly, the research design and the results, in all cases, should be subject to review and evaluation by practicing physicians before policy decisions are made based on the studies. Moreover, the results of a study should be used as guides for physicians, not as absolute rules, so that physicians can continue to tailor medical care to meet the unique medical needs of each individual patient.

Practice Parameters

Practice guidelines, or practice parameters as we like to call them, are tools to assist physicians in the diagnosis and treatment of specific diseases or conditions. They are developed by synthesizing the broad array of medical information, including scientific studies, available data, and expert opinion. They are not like a cookbook, which provides a specified course of action. Instead, practice parameters outline the range of appropriate treatments and procedures for a given clinical situation. The advantage of practice parameters is to identify the boundaries between appropriate and inappropriate treatments. For example, for a patient with heart disease, the parameters would define appropriate treatment options. Through evaluation of the patient's medical condition and personal preferences and through the use of the practice parameters, the physician could then select the most appropriate treatment: such as medication, coronary angiography, coronary angioplasty or a coronary artery bypass operation. Even with parameters, physicians remain responsible for tailoring treatment to what is most appropriate for the individual patient.

The primary purpose of practice parameters is to improve the quality of patient care by helping physicians and patients identify appropriate treatment options. An additional benefit of the parameters may be to control health care costs by reducing the provision of inappropriate or marginally beneficial care.

The development of practice parameters requires considerable input from both practicing physicians and the research community. Input from practicing physicians is needed to make the practice parameters clinically relevant and to take into account the perspectives of the relevant medical specialty societies on the available options for treatment. The research community is needed to provide perspectives on the significance of specific studies and on the latest advances in medicine.

Practice parameters have already been developed by a number of medical specialty societies. Some parameters have been completed in as little as a few months, while others have required considerably more time. The length of time depends on a number of factors, including the number of treatment options, the adequacy of scientific research, the reliability of available medical literature, the degree of clinical consensus and the methodology used.

If practice parameters are developed correctly, and provide information that is clinically sound and useful, practicing physicians will use them. Activities such as the Maine Medical Assessment Program and the guidelines developed by the American Society of Anesthesiologists have shown that physicians will modify their practice patterns to optimize care when they are provided with relevant, well-documented scientific information concerning how to better treat patients.

Other benefits from the development of practice parameters may include a reduction in geographic variations in utilization of medical care services, greater assurance to third-party payors that medical services are appropriate, and an improvement in the professional liability climate. In fact, anesthesiologists in some states already have seen reductions in their professional liability premiums. There are some risks, however, to the development of practice parameters. If the parameters are developed incorrectly, patients might not be provided preferred treatment options, payment denials might occur for medically necessary services, medical innovation might be restricted, and professional liability exposure might be increased.

AMA Activities

The AMA believes the benefits to patients of practice parameters outweigh the risks. Consequently, the AMA has initiated plans to develop practice parameters in collaboration with the national medical specialty societies. These efforts provide the practicing physician and specialty society perspectives as well as the research expertise needed to develop practice parameters properly.

Some medical specialty societies have already developed practice parameters, and others have plans to do so. We encourage these efforts. However, clinical practice issues often cut across several specialties. Practice parameters for these conditions must be based on input from all of the relevant medical specialties.

The example of breast disease illustrates the need for integration and cooperation among the medical specialties. Family practitioners, gynecologists, internists, oncologists, pathologists, surgeons, plastic surgeons, and radiologists are all involved in the diagnosis and treatment of breast disease. It is essential that the expertise and knowledge of all of these disciplines be reflected and coordinated in the parameters concerning how breast disease should be managed.

H.R. 1692

The AMA has reviewed H.R. 1692 and commends you, Mr. Chairman, and Representative Gradison for your interest in the important issue of developing practice guidelines. We support such legislation if modified consistent with the suggestions we will now be making. Specifically, we support the thrust of the section that provides for outcomes, effectiveness and appropriateness research. In our view, however, the definition of effectiveness research should be clarified to ensure that it applies only to the medical effectiveness, not the cost effectiveness, of such research. Moreover, this section should specify that some of the research grants and contracts should be provided to a national medical association such as the AMA, for coordination with other physician organizations.

We support the development of standards for use in the collection and maintenance of research information, the dissemination of research findings and the education of physicians and other providers in applying the research. However, the Secretary should be required to report to Congress concerning the results of such research before any large-scale activity is undertaken for the development of practice guidelines.

We urge that the provisions requiring that practice guidelines be developed by the Secretary be deleted. Such excessive authority should not be granted to the Secretary. The federal government (and other third party payors) should not play a dominant role in the development of practice parameters. Practice guidelines developed by the federal government would not be accepted by physicians, who, with historical justification, would be suspicious that cost savings, rather than quality, would be the government's overriding consideration. Moreover, the government lacks the expertise necessary to develop clinically relevant and scientifically sound parameters. In our view, the broad authorization in the bill would be a dangerous precedent departing from the basic tenets upon which medical practice has developed to date. The federal government should not define what constitutes appropriate medical practice.

Instead, the federal government should oversee the development of guidelines by providing grants or contracts to physician organizations, including the AMA, which then would actually develop the guidelines. Providing financial support to physician organizations would help ensure that clinically relevant and scientifically sound parameters are developed. This would also signal that the federal government is interested in the quality as well as the cost of health care.

The AMA believes that the primary purpose of the guidelines should be to improve the care given to patients by educating physicians. It is premature to plan to use the guidelines to make payment denials. The use of guidelines for screening purposes and for potential payment denial should proceed cautiously and only with the advice of the medical profession.

In our view, the appropriations that would be authorized under the bill are adequate. However, during initial implementation, a greater proportion of the funds should be allotted for the development of practice guidelines in the private sector. We recommend that in FY90, 25% of the funds should be allotted for each of the four purposes specified. In addition, we are concerned that the use of Medicare trust fund revenues may create an inappropriate incentive to find Medicare savings in future years. If possible, funding should come from general revenues.

Finally, we urge that the bill specify that the Advisory Council established under the bill include at least six physicians in active clinical practice to ensure that the Council has adequate medical input.

The AMA also urges that H.R. 1692 be modified as follows:

(1) "Practice guidelines" should be defined as "parameters that identify the range of appropriate tests, treatments, and procedures for a given clinical situation."

(2) Responsibility for overseeing the research and guideline development program should be assigned by legislation to the Office of the Assistant Secretary for Health, which has the necessary medical expertise. In addition, this would ensure that the research and guideline development process is separated from the HHS entity (the Health Care Financing Administration) that makes reimbursement decisions.

(3) The development of guidelines should be prioritized, focusing first on conditions or treatments where there is an adequate and accurate data base for study and a high degree of variability of practice in different geographical areas. Other relevant factors include the frequency, risk and costs involved in treatment alternatives.

(4) The guidelines developed should be pilot tested in selected localities to demonstrate their appropriateness before they are disseminated or implemented on a national basis. Then they should be disseminated to physicians and other health care providers for educational purposes.

(5) If and when clinically relevant practice guidelines are developed and disseminated, physicians must be allowed in a particular case to deviate for good cause from the practice guideline.

(6) The guidelines developed should be reevaluated periodically to ensure that they take into account new medical knowledge.

Conclusion

The AMA strongly supports private sector development, dissemination and implementation of clinically relevant practice parameters. Practice parameters should enhance the quality of patient care by helping physicians and patients identify appropriate treatment options as well as the benefits and risks associated with particular treatments. In addition, practice parameters will be more effective than arbitrary expenditure targets in assuring appropriate utilization.

We believe that the medical profession, in general, and practicing physicians, in particular, should play a leading role in the development of practice parameters. We have demonstrated this commitment with our initiative with the national medical specialty societies. We are hopeful the federal government will provide financial support for projects in the private sector to develop practice parameters.

Finally, we commend you and Representative Gradison for your interest in this important issue. While we support the intent of H.R. 1692 and some of the provisions of the bill, we urge that the bill be modified as noted above.

Mr. Chairman, I will be happy to answer any questions Members of the Committee may have.

Chairman STARK. Thank you.
Professor Reinhardt, welcome back.

STATEMENT OF UWE R. REINHARDT, PH.D., JAMES MADISON PROFESSOR OF POLITICAL ECONOMY, WOODROW WILSON SCHOOL OF PUBLIC AND INTERNATIONAL AFFAIRS, PRINCETON UNIVERSITY, PRINCETON, NJ, AND PRESIDENT-ELECT OF ASSOCIATION FOR HEALTH SERVICES RESEARCH

Mr. REINHARDT. Thank you very much, Mr. Chairman and members of this committee.

I am Uwe Reinhardt, professor of political economy at Princeton University, and president-elect of the Association for Health Services Research [AHSR].

The AHSR is a national professional association of health services researchers and users of research. It includes over 1,200 individual members and close to 80 institutional members throughout the United States. The association is dedicated to promoting, strengthening, and improving the field of health services research.

I appreciate this opportunity to testify on behalf of the AHSR in strong support of H.R. 1692. This bill is timely and supports the truly important, but hitherto much neglected facet of our health care system, and that is the study of how to obtain the best value in terms of outcome that can be had from our growing health care expenditures.

Americans like to be world leaders in all manners of human endeavor. I can assure you that passage of this bill will make America the world's leader in quality assessment and quality assurance within the next two decades.

One of the major goals of the AHSR has been to develop an infrastructure for health services research. The development and implementation of a sustained multidisciplinary research agenda is the only way we will be able to attract the best minds to this field and to build a knowledge base over the next decade that will be useful to health professionals, consumers, payors, and policymakers.

Ten years from now, I am sure that Drs. Brook, Ellwood, Wennberg, and Palmer will still be the leading figures in this field. However, we hope that, at that time, there will also be a much longer list of other experts advancing and challenging the research effort of our medical system.

At this time, it's been actually rather difficult to persuade young people to invest their lives in this field because funding has been so capricious and is actually declining. We feel that this bill is one of the first signs we can see that society wishes us in this field to bring young people into the field and to invest their lives in it.

We have some specific comments on the bill that we would like to share with you and that you may wish to consider in refining this bill further.

First, AHSR believes that it is important to conceive of outcomes research in very broad terms and not just view it as clinical research. For example, the way health care is financed affects outcomes. Cost sharing, as Dr. Brook mentioned, affects what people

seek in health care, and it has so far cut both appropriate and inappropriate care.

We would like to know the effect of prepayment on outcomes, the effect of alternative delivery systems, and we would urge you to define outcomes research broadly enough to embrace these types of studies.

Second, we believe that dissemination of information should not only go to providers but to the public as well, that there should be public education, and as part of that, we shall have to learn how best to present such information to consumers in a manner that is useful for them. So, outcomes research, in our view, should include experimentation in communicating health information to the consumer.

We support the notion of funding this bill from both the Medicare trust fund and general revenue so we can embrace a somewhat broader set of patients than would be implied simply with trust fund financing.

Now, AHSR believes that it is vitally important to pass this outcomes research program this year. In addition, we would suggest that you consider the program as one key element within a broader health services research agenda that goes beyond outcomes research per se.

As you will note from our testimony, AHSR believes that the time has come to give health services research the kind of visibility that would come with an agency status within the PHS. And in that connection, we would simply endorse the remarks Dr. Mason had made that it is probably best for the scientific basis of this research that it be housed in the PHS. And within it, we don't, at this time, have any specific comments to make, but we would like to explore the ability to give this whole thrust more visibility than it has had in the past, perhaps through the vehicle of an agency within the PHS.

I was delighted to be able to testify before you and I will be happy to answer any questions you may have.

[The statement of Mr. Reinhardt follows:]

Statement of Uwe. R. Reinhardt, Ph.D.,
President-elect of the
Association for Health Services Research,
on H.R. 1692,
the Medical Care Quality Research and Improvement Act of 1989,
to the
Subcommittee on Health of the House Committee on Ways and Means
May 24, 1989

Mr. Chairman and members of the Committee, I am Uwe R. Reinhardt, Ph.D., a professor of political economy at Princeton University, and President-elect of the Association for Health Services Research (AHSR).

The AHSR is the national professional association of health services researchers and users of research. It includes 1200 individual members and 75 institutional members throughout the United States. The Association is dedicated to promoting, strengthening, and improving the field of health services research.

I appreciate this opportunity to testify on behalf of AHSR on H.R. 1692, "The Medical Care Quality Research and Improvement Act of 1989", and to support the establishment of a national program of research on the outcomes, effectiveness, and appropriateness of medical care.

The panel of experts that you just heard -- John Wennberg, M.D.; Robert Brook, M.D.; and Paul Ellwood, M.D. -- exemplifies far better than I can describe some of the pathbreaking work that has been done thus far. And, they point out the opportunities available to develop and apply new knowledge in these areas. This morning, I would like to review the need for such research, comment on H.R. 1692, and present AHSR's views about the need for an even broader health services research framework within which to support this important effort.

The need for research on outcomes, effectiveness, and appropriateness

The opportunity to enhance our knowledge base in order to improve the medical care that we provide is, in my view, reason enough to embark on this research effort. However, the need is reinforced by two other factors. First is the fact that the studies done thus far indicate that there is a problem, and that it is one which can be addressed. As the experts on the preceding panel have indicated, research performed during the past decade has discovered that there are substantial unexplained variations in medical practice throughout the country, that some services which are performed do not achieve the results intended, that some are inappropriate for some patients, and that we can in fact develop the information that will allow us to do a better job of understanding these matters and improving our health system.

Second, the wide, inexplicable regional variations in per-capita utilization of health care and the more pointed studies on the appropriateness of specific procedures raise serious questions about the concrete value that is being achieved with this nation's high health care expenditures. As this Subcommittee is well aware, Federal health care spending will increase by about $18 billion to a level of $155 billion in FY 1990, even <u>after</u> the budgetary constraints that Congress seeks to impose on Federal health spending. Furthermore, as the members of this Subcommittee are aware as well, the United States spends more on health care per capita, and as a percentage of the GNP, than does any other nation in the industrialized world. It is now generally agreed that the recent high growth trends in health care expenditures cannot be sustained indefinitely without seriously eroding other major national efforts, among them the education of the nation's young. It is therefore doubly

important to produce a knowledge base capable of helping decisionmakers in health care to maximize the value of output per dollar of health care expenditure.

The research to be initiated by this bill, however, should not be viewed as a means of achieving short-term savings. A substantial period of time will be required for any changes in practice throughout the medical care system. Further, enhanced knowledge about what is most appropriate will help educate both the profession and policymakers about the need for action on cases where the appropriate services are not provided, in addition to cases in which inappropriate services are provided.

Rather than looking to this research effort as a "magic bullet" for constraining spending, I would look to it as an effort to improve quality and as a vehicle for helping to assure that the service and resource allocation decisions within health care are based on the best available information. If that were the case, we would have a stronger sense than we have today that we are spending our money on health care appropriately, and that we have information that will allow the health system to respond to any subsequent constraints on the resources that we do devote to health care.

H.R. 1692

The AHSR commends both Mr. Gradison and Mr. Stark for developing H.R. 1692, and strongly supports this initiative to enhance our efforts in the four areas outlined in the bill:

- o research on outcomes, effectiveness, and appropriateness;
- o standards for the creation of databases which will enhance the research effort;
- o dissemination of the findings and education of providers; and
- o the development of practice guidelines.

The AHSR would like to share some comments on the bill for you to consider as part of our recommendation that you approve this research program.

First, we believe that it is very important in this endeavor to allow substantial amounts of discretion for funding a diverse array of research on outcomes, effectiveness, and appropriateness. You have heard this morning from a panel of individuals who can be described as the world's leading experts on this subject -- and Heather Palmer, on the panel with me now, ranks with that group. It is important to note, however, that all of the approaches being described differ somewhat, and that the breadth of our expertise on this subject is far too thin. It is imperative that we pursue a variety of multidisciplinary research opportunities and encourage continuing creativity and diversity in research approaches.

The approach to outcomes research should even be viewed more broadly than assessments of clinical protocols. For example, we need a better understanding of the impact of non-clinical factors on outcomes. These include further studies of the impact of alternative means of organizing the financing and delivery system, or of varying provider financial arrangements, on practice patterns and outcomes. Dr. Brook provided examples of studies of this type, such as the evaluation of the impact of the California Medicaid cutbacks on health outcomes, and the RAND health Insurance Experiment, which assessed the impact of various health insurance coverages on health outcomes. We need more research like that, to combine with the clinical outcomes research, in order to give us a broad understanding of how our health system might best meet the health needs of the American

people. We also need to fund additional work on the development of the basic methodologies which can be used to implement policy and to perform the research. Past funding of research led to the development of DRGs to pay hospitals. Current and future research will have to provide the patient classification and outcome measurement methods that will be used in developing and implementing practice guidelines.

The development and implementation of a sustained, multidisciplinary research agenda is the only way that we will attract the best minds to this field and build a knowledge base over the next decades that will be useful for health professionals, consumers, payors, and policymakers. Ten years from now, I am sure that Drs. Brook, Ellwood, Wennburg, and Palmer will still be leading figures in this field. However, I hope that the Subcommittee -- and the health system generally -- will have access to a long list of other experts advancing and challenging the research efforts and the medical system. Collectively, these experts ought to be viewed as a national resource of "human capital."

I am afraid that, as a nation, we have generally been insufficiently attentive to nourishing and maintaining our stock of human capital, not only in this but also in other areas. One of the ways to detract from that capital stock, for example, is instability over time in the funding of research. As an educator, I can assure you that it is extremely difficult to persuade young people to specialize in the production of public information when that activity is capriciously funded by society. H.R. 1692, we believe, will go far in reducing the risk young persons face when they decide to invest their human capital in specialized health services research of this sort.

Second, the AHSR strongly supports the direction in H.R. 1692 providing for provider education and dissemination of information to the provider community, but we believe that we should go even further. We believe that public education is a critical element in improving the appropriate use of medical services and, ultimately, health outcomes. Individuals who understand more about medical treatments and their outcomes can be better consumers and can be more directly involved in decisions about their own care. It is important that we first learn how to present such information to consumers in a manner that will be useful to them, and that we identify effective dissemination approaches that will reach the public. This may involve working with national magazines, television, and radio, as well as preparing and disseminating specially designed educational materials to be given by providers to their patients.

Third, the AHSR supports the funding levels in the bill and commends you for including funding from both Medicare Trust Funds and general revenues. The research program envisioned should benefit the aged and disabled, as well as the rest of the population, and the blend of financing in H.R. 1692 reflects that balance.

Fourth, the AHSR supports the bill's use of an external advisory committee to provide broad input into the research priority-setting process. In addition, we support the bill's establishment of an internal coordinating group to integrate outcomes research-related activities among the various components of DHHS. Finally, we are supportive of the designation of the Assistant Secretary for Health in the lead role for that coordinating group, and have some additional thoughts about administration of the research program which I will get to later in my testimony.

Broad Framework for Research

The AHSR believes that it is vitally important to pass this outcomes research program this year. In addition, we would suggest that you consider the program as a key element within a broader framework and program for health services research.

The Congress and the health community confront an extremely complex array of issues in health care. Your Subcommittee continually has to grapple with difficult issues, and you are often asked to make political choices in the absence of good, objective information. As I noted earlier, the Federal government will spend more than $155 billion on health care in FY 1990 -- and you need information. The AHSR Board has spent over two years deliberating on the Federal role in health services research, and has concluded that we need a greatly expanded and sustained effort to enhance our knowledge, not just of outcomes and effectiveness, but on a broad range of key issues of concern to you and your Congressional colleagues.

Outcomes research is a prime example of where a greatly expanded research effort is needed, but it is not the only area in which there is a critical need to improve our knowledge base on matters that are vital to this Subcommittee and the Congress. For example, we need to know more about hospital productivity. In an era of continuing constraint on resources, information on facility and system productivity will be essential both to the Congress and to health providers in developing and coping with revisions in the payment systems. We also need to know more about hospital and health system capital financing, about rural and inner city health service and delivery issues, and about financing and paying for physicians' services. The Subcommittee is dealing with complex issues related to financing care for the 37 million uninsured, and questions about how best to revise and finance a long-term care system that will meet the needs of our aging population. The research community cannot answer the difficult political issues that confront you in those areas -- but a sustained Federal health services research effort is the only tool you have to inform those highly charged debates.

The Board of the AHSR has concluded that the breadth and importance of the research effort confronting us calls for a prominent new focal point for Federal leadership in health services research -- including the outcomes and effectiveness research effort. H.R. 1692 appears to suggest that the Assistant Secretary for Health would assume that leadership for outcomes and effectiveness research, and chair a coordinating group within the Department of Health and Human Services. The AHSR agrees that the Assistant Secretary for Health and Public Health Service are the appropriate focal point, but would go further.

We believe that it is necessary to establish a new agency in the Public Health Service to provide the sustained level of support and leadership for the broad-based health services research program that is now required. We believe that such research should be conducted in an agency whose basic mission is the conduct of professional, scientific research, and that it is most appropriate to locate such an entity within the Public Health Service (PHS). The entity will need to build on and maintain the PHS's ongoing linkages with the clinical medical community, the research community, and the education community as it develops the necessary training programs and research infrastructure and expertise that will be required to actually perform the research that is envisioned.

However, while the research would be performed by such an agency, we want to be clear that we strongly support your proposal to authorize the outcomes research program in the Social Security Act so that your Committee will be assured of maintaining leadership and jurisdiction over the outcomes research program, as is the case in H.R. 1692. We also believe that HCFA should retain its ongoing programmatic research

responsibilities, and should play a large role in influencing the broader research agenda, as your bill proposes.

Conclusion

In conclusion, Mr. Chairman, the AHSR strongly supports the general program outlined in H.R. 1692. We thank Mr. Gradison and you for your leadership and we urge the Subcommittee to approve the research program with the minor changes elaborated in this testimony. We also ask that you eventually combine it with a broader health services research program under the leadership of a new health services research agency.

The AHSR appreciates this opportunity to present our views, and would be pleased to provide any further information or assistance to the Subcommittee or the staff.

Thank you.

Chairman STARK. Thank you very much.
Dr. Palmer.

STATEMENT OF HEATHER PALMER, M.B., B.CH., S.M., BOARD MEMBER, AMERICAN MEDICAL PEER REVIEW ASSOCIATION, CHAIRPERSON, AMERICAN MEDICAL REVIEW RESEARCH CENTER, AND LECTURER ON HEALTH SERVICES AND ASSOCIATE DEAN FOR STUDENTS, HARVARD SCHOOL OF PUBLIC HEALTH

Dr. PALMER. I am Heather Palmer, a physician engaged in health services research, a board member of the American Medical Peer Review Association, the National Association for Physician Directed Medical Review Organizations, including the federally designated peer review organizations. I am chairperson of the American Medical Review and Research Center, the research and education affiliate of AMPRA, which strives to link the health services research community with PRO's in collaborative efforts to conduct medical outcome research and test innovative quality review and utilization management strategies.

AMPRA is most appreciative of the subcommittee's invitation to present our views and recommendations on H.R. 1692.

I would like to comment on several critical stages in the national medical care effectiveness strategy. The first stage, outcomes research and effectiveness and appropriateness research, is an urgent necessity. The PRO community deals on a daily basis with the issue that physicians have to struggle with great uncertainties when making decisions about the probabilities of benefits and risks to their patients.

PRO's also have constantly to cope with the severe limitations of our existing data bases on patient care. The fragmented setting-specific data bases do not permit the tracking of patients through the continuum of care delivery. A longitudinal data base will be imperative if we are to be serious about monitoring and analyzing patient outcomes.

We believe both public and private sectors have to invest in collecting more information on patients, and that patients themselves should be asked to contribute information.

AMPRA is encouraged by the work that has begun within the Health Care Financing Administration, in integrating and improving the Medicare data base. AMPRA believes that a sound investment is needed now in better data bases, which will provide exciting and rich opportunities for research in health services, and will also permit practicing clinicians to monitor their own impact on the illnesses of their patients.

The next step in the strategy is the development of appropriateness specifications by combining results of outcome studies, using consensus methods and decision science. AMPRA has been impressed by the work of the RAND Corp. in using consensus methods to develop appropriateness specifications, and is encouraged by the increasing commitment of specialty societies and the American Medical Association. Nevertheless, it is extremely important to recognize that these detailed specifications often involve several hundred explicit decision rules for a particular condition or procedure.

They are not in a form that can be used by busy practicing physicians. The detailed specifications need to be translated into guidelines for physician use. AMPRA believes that this step will need to precede an educational program for practicing physicians and physician managers.

To date, efforts have stopped at consensus building, and at somewhat cursory efforts to disseminate findings. AMPRA believes that even a formal program of education of physicians and physician managers about guidelines will not be enough to cause physicians to adopt them. Health services research shows that the effective way to encourage physicians to change their practice in appropriate directions is to evaluate their performance, and feed back the findings through peer review mechanisms.

So developing guidelines is not enough. We must create medical review criteria to evaluate physician performance and feed back that information to physicians.

AMPRA believes strongly that criteria and standards must not be applied rigidly in payment decisions. There must be flexibility using peer review to allow physicians to use good judgment when adjusting to unique patient characteristics, to the availability of local resources, and to physicians' own particular competencies.

In addition, AMPRA believes that it is important to translate appropriateness specifications for patients as well. This is particularly true when medical uncertainty still exists even after development of practice guidelines. Patients must understand the risks and benefits associated with medical treatment.

AMPRA believes that the PRO community can contribute its resources and expertise to this agenda. In particular, AMPRA is supportive of the goals and the intent of H.R. 1692, and is also examining the proposals by Senator Mitchell and the one we anticipate from Congressman Waxman.

AMPRA is encouraged by the convergence of opinion on the need for legislation in this area. It recommends to the subcommittee that the PRO program be considered as an administrative mechanism to test the application of practice guidelines. It also recommends that, as participants in outcomes research and practice guidelines development, and end-users of the guidelines and criteria, serious consideration should be given to representatives of the physician peer review community taking a place on the proposed National Advisory Council.

Mr. Chairman, I am grateful for the opportunity to testify on behalf of AMPRA. We want to thank you for this opportunity and offer to answer any questions.

[The statement of Dr. Palmer follows:]

WRITTEN STATEMENT
American Medical Peer Review Association
on the
"The Medical Care Quality Research and Improvement Act of 1989"
to the
Subcommittee on Health of the House Committee on Ways and Means
May 24, 1989

Mr. Chairman, and members of the Subcommittee, I am Heather Palmer, M.B., B.Ch., S.M., a physician engaged in health services research, Board Member of the American Medical Peer Review Association (AMPRA), Chairperson of the American Medical Review Research Center (AMRRC), and Lecturer on Health Services and Associate Dean for Students, Harvard School of Public Health. AMPRA is the national association for physician directed medical review organizations, including the federally designated Peer Review Organizations (PROs). AMRRC is the research and education affiliate of AMPRA, striving to link the health services research community with PROs in collaborative efforts to conduct medical outcome research and test innovative quality review and utilization management strategies. At present, AMRRC is involved in a HCFA-sponsored project to make available Medicare small area analysis data to each PRO in the country for use in provider education and feedback, and for targetting medical review interventions.

AMPRA is most appreciative of the Subcommittee's invitation to present our views and recommendations on H.R. 1692, the Medical Care Quality Review and Improvement Act of 1989. Our written statement will discuss why a national medical effectiveness strategy is needed, the elements of such a strategy, the role of various constituent groups, the strategy's relevance to the medical review community, and specific views and comments on the bill, H.R. 1692, as introduced.

DEFINITIONS

At the outset Mr. Chairman, it is important that we arrive at a common understanding of certain terms -- guidelines, parameters, criteria and standards -- that tend to be used interchangeably in discussing this topic. For the purposes of AMPRA's testimony, we would like to make the following distinctions. The end result of combining the analysis of present scientific/knowledge on medical effectiveness with expert consensus methods are specifications for appropriateness of care. Guidelines or parameters represent the translation of these often detailed specifications, which might involve several hundred explicit clinical indicators for appropriate care, into statements that can be easily used by practicing physicians as a tool in their own clinical decision making. Medical review criteria and standards, represent the translation of these appropriateness specifications into useable formats that can be applied in quality assurance and utilization review programs. Criteria identify elements of health care for which performance is to be measured. Standards set levels for acceptable compliance with criteria: if the level is not reached, intervention is triggered. A point that we will echo later in our testimony, AMPRA believes that criteria and standards must not be applied rigidly in making payment decisions. There must be flexibility, understanding that unique patient characteristics or demands, availability of local medical resources, or individual professional judgement will require deviation from the standard.

WHY IS A NATIONAL MEDICAL EFFECTIVENESS STRATEGY NEEDED?

Mr. Chairman, you and your distinguished colleagues are well aware of the health care research that has demonstrated significant variation in the rates of medical practice in our country. This variation reflects the fact that medicine today is still governed by art as well as science. Medical uncertainty is the constant companion of the practicing physician and many clinical decisions are made based on what is possible, not what is probable. The range of probabilities as currently known is too great to provide a basis for decision. Put another way, medical treatments are provided when it has not been clearly determined that the benefits to the patient outweigh the associated risks. I do not subscribe to the view that physicians consciously deliver inappropriate services. I believe physicians attempt to do what they think is best for their patients. The problem stems from the fact that we lack scientific evidence of the effectiveness of various treatments and what evidence we do possess is unevenly disseminated and often in a form not readily absorbable by the practicing physician.

The development of a national medical effectiveness strategy can help address this information gap in medicine today. There will be multiple rewards: medical uncertainty reduced; quality of care improved; malpractice costs reduced; overall cost containment through reduction in inappropriate medical care services. It will not, however, solve all our problems. Access to care, long term care, disease prevention, inadequate financing and a host of other complex problems will remain. But recognizing the value of a societal investment in determining what works and does not work in medicine is an important part of our national health care agenda.

ELEMENTS OF A NATIONAL STRATEGY

Mr. Chairman, from AMPRA's perspective there are six critical stages in a medical effectiveness strategy:

1. **conduct** of outcome research;

2. **development** of specifications for appropriateness of medical care based on the analysis of the scientific evidence of medical effectiveness combined with expert consensus methods and other tools of information decision science;

3. **translation** of specifications into guidelines for practicing physicians and criteria for medical reviewers;

4. broad **dissemination** of outcomes research, guidelines and criteria to practicing physicians and the medical review community;

5. **application** of guidelines and criteria by physicians in making clinical decisions and reviewers in making final determinations;

6. **re-assessment** on a continuing basis of the use of guidelines and criteria for the purpose of refinement as new scientific evidence comes on line.

Each stage in the process is critical to the overall success of the effort. The first stage, outcome research, is an expensive, multiyear, complex undertaking, relying on sophisticated randomized clinical trials and epidemiological studies. AMPRA is pleased to see the recent progress that has been made to increase federal funding, but major new dollars need to be committed and the private sector must participate.

The complex task of outcome research would be made easier if the public and private sectors made a commitment to integrate and improve existing data bases. Fragmented, setting-specific data bases do not permit the tracking of patients throughout the continuum of medical care delivery. A longitudinal data base is imperative if we are serious about monitoring and analyzing patient outcomes. Such a database could bring together the results from a very large number of natural experiments in which alternative therapies are applied to similar conditions.

At the same time, the public and private sectors must invest in collecting far more information on a patient's condition at different intervals in medical care delivery. This effort must involve: the collection of more objective clinical data than is presently reported on either ambulatory or inpatient claims; the development of a data base on the functional status of patients; the collection of information directly from the patient. Patient generated information is often overlooked, but must become an important element of our database development. This is particularly true in assessing the quality and effectiveness of ambulatory care management given the lack of information on ambulatory claims.

AMPRA is encouraged by the work of the Health Care Financing Administration (HCFA) in integrating and improving the Medicare data bases. The common working file effort that will merge Part A & B data, the development of a Uniform Clinical Data Base, the inclusion of diagnosis on the HCFA claim 1500; the development of a Uniform Needs Assessment Instrument are all efforts leading in the right direction. As the Medicare Catastrophic Health Care bill is phased in, and Medicare becomes responsible for outpatient drug expenditures, information on beneficiary drug usage will be available to extend the analysis of patient outcomes.

Mr. Chairman, we believe that a sound investment now in database development will make the job of outcome and effectiveness research and analysis far easier and less expensive. It will provide exciting and rich opportunities for health services research, but will also permit practicing clinicians to monitor their own impact upon the illnesses of their patients.

The next step in the process of developing a national effectiveness strategy is the development of specifications. AMPRA has been impressed with the work of the RAND Corporation in using consensus methods in developing appropriateness specifications. The increasing commitment of specialty societies and the American Medical Association is encouraging as well.

Mr. Chairman, AMPRA is concerned, however, that efforts to date have stopped at consensus building and cursory efforts to disseminate findings. Even a formal program of education of physicians and physician managers about guidelines will not cause those physicians to adopt them. Health services research shows that the effective way to encourage physicians to change their practice in desired directions is to evaluate their performance, and then feedback the findings through a peer group mechanism. Work must proceed not only through the phases of translation and dissemination but also through the phases of translation and dissemination but also through application of criteria in medical review and re-assessment. As emphasized earlier, application of medical review

criteria includes evaluation of physician performance and feedback to physicians. Each stage is critical and must be included in any coordinated national strategy. AMPRA is also concerned by the fact that RAND appropriateness specifications developed by public monies have been translated into medical review criteria by a proprietary firm and are now being marketed privately. AMPRA believes that the entire process represents a public good and thus should be an open exercise that receives public support.

ROLE OF VARIOUS PLAYERS

As a public good, the various players in the health care community have an interest and a role in the national medical effectiveness strategy. The academic health care research community must obviously take the lead in conducting outcome research. The same academic research community must work with organized medicine, a consortia of specialty societies, and other physician experts in developing appropriateness specifications through analysis of outcome research and applying the tools of information decision science. Included in this same task must be the translation of specifications into workable guidelines for practicing physicians and workable criteria for medical reviewers, and the feedback to physicians of their performance as measured by peer review.

It will also be important to translate appropriateness specifications not only for practicing physicians and reviewers but patients as well. This is particularly true when medical uncertainty still exists even after the development of practice guidelines. In these instances, patients must understand the relative risks and benefits associated with medical treatment and the patient must become an active partner in treatment decisions.

Broad dissemination of these various products to practicing physicians reviewers, and patients can be a shared responsibility for multiple parties including organized medicine, public and private payors of care, PROs, consumer groups, and others.

The responsibility of evaluating the use of guidelines and criteria must be shared by the end users together with the academic and physician experts who developed them. Ongoing refinement of guidelines and criteria must be the logical extension of this evaluation effort.

Funding this effort must be the primary responsibility of the public and private payors of care. The federal government, representing the Medicare and Medicaid programs, must take the lead but state government and private payors of care must commit to follow.

Mr. Chairman, AMPRA believes that only a coordinated national strategy can ever hope to tie together the various players and elements involved in medical practice development and use. The present state of fragmented uncoordinated, disparate activities and projects now underway in both the public and private sectors will not effectively address the need at hand.

RELEVANCE FOR THE MEDICAL REVIEW COMMUNITY

Mr. Chairman, we in the medical review community feel a special kinship to this emerging national medical effectiveness strategy. Determining what is and is not effective, appropriate, quality care is the challenge and goal of any medical review effort. We believe that the end products of this national strategy can greatly assist the PRO community in its job of medical care evaluation.

AMPRA also believes that the PRO community can contribute its own resources and expertise to this overall strategy and needs to be integrated into the various stages of the process. Specifically, the PRO community can play a role in:

1) outcome research through collaborative efforts with health services researchers, using PRO databases, PRO access to medical records, and PRO analytic expertise;

2) establishing appropriateness specifications and translating that work into medical review criteria through the contribution of individual physician experts involved in the PRO program;

3) the dissemination of guidelines to practicing physicians through the link provided by our medical review activities and the dissemination of review criteria to AMPRA's network of medical review organizations;

4) the application of criteria in evaluation of physician performance and feedback to physicians on their performance;

5) the evaluation and refinement of guidelines and criteria through the knowledge gleaned from having used the tools in the real world and by the incorporation of new scientific evidence.

AMPRA's research affiliate, the American Medical Review Research Center (AMRRC), is already working on projects related to these activities and would be another excellent resource to call on in designing and executing our national effectiveness strategy. There is an extensive community of health services researchers with expertise in the field of medical care quality. Most of us received our training in universities supported in part by federal monies through the National Center for Health Services Research and the Office of Research and Demonstrations at HCFA. The time has come to reap the rewards of this investment. Just as the fruits of outcomes and effectiveness research must be disseminated to practicing physicians, so the fruits of health services research must be disseminated to practicing reviewers of the quality of care. This is now the main mission of AMRRC. We have co-sponsored with the Accreditation Council for Continuing Medical Education (ACCME), the American Medical Association (AMA), the American Association of Medical Colleges (AAMC), PROs and others, a conference on remedial education for physicians found to be practicing inappropriately and ineffectively. AMRRC with AMPRA is working through committees of health services researchers and PROs to develop PRO pilot projects to field test better methods for quality review. We plan a working conference this fall in which health services researchers and PROs will work together on initiatives in outcomes and effectiveness research. Through these and other efforts we will amplify the impact of outcomes and effectiveness research on actual patient care.

Mr. Chairman, I would like to comment briefly on how we in the PRO community envision using the products of this national endeavor. We would like to reiterate our earlier position that the appropriateness specifications developed through consensus techniques must be translated into medical review criteria. We believe if this step is performed, PROs around the country will, of their own volition, use the medical criteria in the PRO review process. In this regard, however, we want to make clear that even with more explicit, empirically based medical criteria being applied, final medical review decisions must be based on sensible medical judgements that, on an individual case basis, can take into account unique patient characteristics or demands, knowledge of the local medical care resources, and the social needs of an often chronically-ill elderly or indigent patient. Providers and practitioners must also be provided with appropriate due process that permits opportunities for pre-denial notifications and reconsiderations. In short, physicians and reviewers must maintain the flexibility to deviate from the criteria or standard when medical judgement dictates a different course of action.

COMMENTS ON H.R. 1692

Mr. Chairman, AMPRA is supportive of the goals and intent of H.R. 1692, The Medical Care Quality Research and Improvement Act of 1989. We look forward to working with you, Congressman Gradison (R-OH), and all other members of the Subcommittee in your continuing efforts to fashion a national strategy for the study of medical practice. We are also reviewing the proposal by Senator Mitchell (D-ME) and anticipate, in the near future, a proposal by Congressman Waxman (D-CA). AMPRA is encouraged by the convergence of opinion on the need for federal legislation.

The following are our specific comments to H.R. 1692:

Dissemination of Findings and Education of Providers -- Mr. Chairman, the Committee may want to emphasize the importance of proceeding in tandem on the conduct of outcome research, the development of practice guidelines and plans for dissemination of findings and educational programs for providers. We make this suggestion because it has been our experience that research findings are not easily digestible by practicing physicians. Indeed, the goal of guideline development is to take, often esoteric and complex scientific findings and translate them into workable and understandable instructions or clinical algorithims that can be useful tools in making appropriate treatment decisions. If information dissemination followed guideline development, it is our belief that the potential for educating providers would be enhanced.

In addition, we encourage the Committee to endorse the extension of its strategy beyond educating physicians about guidelines to applying the substance of those guidelines in peer review activities and in making plans for the translation of guidelines to information suitable for use by Medicare beneficiaries.

Development of Guidelines -- We applaud the proposed legislation's emphasis on the development of practice guidelines and the recognition that "other entities may use such guidelines in reviewing quality and appropriateness of medical care."

AMPRA is also supportive of the provision mandating the application of guidelines to at least three clinical treatments or conditions. We recommend to the Subcommittee that the PRO program be considered as a logical adminsitrative mechanism to test the application of guidelines. PROs could both disseminate guidelines to practicing physicians and apply guidelines, that have been translated into review

criteria, to evaluate medical treatment. Since PROs are presently precertifying 100 percent of ten high-frequency, high-variation Medicare procedures, the Subcommittee may want to consider this current PRO initiative as a specific testing ground for guideline application.

Advisory Council -- As participants in outcomes research and practice guidelines development and end users of the products that will emanate from this effort, AMPRA believes that serious consideration should be given to including representatives of the physician peer review community in the national Advisory Council. We are appreciative, Congressman Gradison, of your recent remarks at AMPRA's Legislative Policy Conference, in which you recognized the relevance of this national legislation to the PRO community and the importance of encouraging our input.

Funding -- AMPRA is supportive of the aggregate funding level, for H.R. 1692. We believe that some consideration should be given to private sector support for this national program. Just as the public and private sectors will both share in the benefits of this effort, so too should the public and private sectors share the financial burden.

AMPRA also recommends that some further consideration be given to the division of funding levels for the various activities the legislation envisions supporting. AMPRA believes that of the activities described, research should receive the greatest funding support, and therefore, we would recommend an increased allocation for this activity. Support for the remaining activities should be equally distributed among: standards for research information; development of guidelines; dissemination of findings and education of providers.

Mr. Chairman, on behalf of AMPRA, AMRRC and its members, I want to thank you, Congressman Gradison, and the other members of the Subcommittee for giving me the opportunity to present our views and recommendations on developing a national medical effectiveness strategy. AMPRA is supportive of the goals of H.R. 1692 and is eager to work with the Subcommittee to advance these important initiatives.

Chairman STARK. Thank you very much.

Mr. Gradison.

Mr. GRADISON. Thank you, Mr. Chairman.

I have one question which I would like to address to any of the panelists who wish to comment on it, and that is how can we structure these efforts in the most effective way from the point of view of gaining physician support for the final product, if you will, that comes out of these initiatives as it deals with the appropriate care for a specific procedure.

Dr. MCAFEE. Mr. Gradison, let me rely upon my experience with our project in Maine, which I think has demonstrated that a very significant part of making physicians change behavior where change needs to occur must depend upon the single greatest motivating factor that physicians have.

It may surprise you that the greatest motivating factor is not necessarily economic, is not sanctioning by loss of license, and is not the threat of action by a credential committee. The Maine project has proven beyond a reasonable doubt, that the fear of loss of the trust and respect of a fellow peer by continued aberrant behavior is the single greatest factor motivating physicians to change their behavior.

Any time that you interject something between that physician-to-physician relationship, you lose something in the ability to accomplish what you want to. And I cannot emphasize that enough. We tried other things in Maine, and they just do not work. Economic sanctions may give you temporary changes. But I think whatever formula we utilize must be done within the context of physician-to-physician relationships because physicians understand, by virtue of practicing day-to-day, and caring for patients, what these guidelines or parameters ought to be.

I think we tried in this country in the past with the PSRO program and the health planning program to create an environment in which we could accomplish certain goals. However, the absence of practicing physician input in those programs was a mistake. I would hope that we realize that physicians have got to be on board from day 1 to help develop clinically relevant guidelines.

Mr. GRADISON. In general, do you think that the specialty and subspecialty groups themselves would have an interest in being the principal investigators? That is, applying for the grants to study the areas within their specialty, within their professional competence?

Dr. MCAFEE. I think they would in those areas where the specialty societies have demonstrated their expertise to date. The American College of Physicians, and the American College of Cardiology already have made a significant commitment to develop practice guidelines.

The problem is, however, that very few diseases are single-specialty oriented. They cross specialty lines, and that is why a more global physician organization, such as the AMA, may be the best way to bring together the various specialty society perspectives. It is obvious that there are many different specialty societies involved in the treatment of heart disease. Also if one looks at breast disease, there are a half dozen specialties who must contribute to finding new knowledge in that field.

Mr. GRADISON. Thank you, Doctor.

Dr. Palmer.

Dr. PALMER. Yes, Mr. Gradison. AMPRA believes strongly that it will be very important to have an ongoing process of review and refinement of guidelines and criteria. When guidelines are put into practical use in different localities, the feedback that is obtained from reviewing actual patient cases is very helpful in understanding places where the guidelines and criteria may be artificially rigid and inappropriate. There has then to be an ongoing process of development of both guidelines and criteria.

Mr. GRADISON. Thank you.

Dr. Reinhardt.

Mr. REINHARDT. I would simply add that it is terribly important that this legislation not be perceived as being driven by economics, as Dr. Mason put it, that it should be based on good science. And it is our belief in the AHSR that if the perception is there that this is driven by the search for good science, that it will be acceptable to the medical community.

Mr. GRADISON. Thank you very much.

Thank you, Mr. Chairman.

Chairman STARK. Mrs. Johnson.

Mrs. JOHNSON. No questions, Mr. Chairman.

Chairman STARK. If I might, Dr. McAfee, let me ask, what goes on in Dr. Kelly's Office of Quality Assurance? You conduct research programs there?

Dr. MCAFEE. Do you want me to answer that or Dr. Kelly?

Chairman STARK. Dr. Kelly, or if you know Dr. McAfee. I thought perhaps you directed that. But if not, Dr. Kelly.

Dr. KELLY. Mr. Chairman, one of the major activities that we are currently involved with is in helping to facilitate and coordinate the broad array of activities already underway and continuing to expand in the various medical specialty societies.

We have had a number of meetings with them to begin to look at a number of very technical issues as to how some of this information, which is already being generated and promises to continue to be generated, can actually be translated into guidelines for clinical practice so that practicing physicians can take this information and put it into the actual treatment of patients. That is one of our major activities.

The other part of our activities is identifying ways in which we can work with a variety of the academic research centers so that we can help guide some of their information, provide proper input to their research activities, and help facilitate translation of that material into clinically useful information.

Chairman STARK. How many people work in your office?

Dr. KELLY. As you know, the AMA is a large organization. Part of the thrust of our activity is to coordinate our activities with the broad array of divisions throughout the building and, so, as such, we have the staff, individuals in my own division, which consist of a staff of 10; we have additional staff individuals throughout the science and technology area, as well as——

Chairman STARK. You have 10 in your division that work for you?

Dr. KELLY. That's correct.

Chairman STARK. What is your budget roughly?

Dr. KELLY. I can provide you with the details of that information, Mr. Chairman, in a separate communication so I can give you accurate information.

Chairman STARK. Do you want to make a guess to the closest hundred thousand?

Dr. KELLY. We have a budget around $750,000.

Chairman STARK. So you have $750,000. So if the President of the AMA worked for you, you would double your budget, huh? [Laughter.]

Is that about correct?

Dr. KELLY. Mr. Chairman, I think that——

Chairman STARK. He gets $700,000, so if they assign him to your office, you could double your budget, is that right?

Dr. KELLY. Mr. Chairman, I'm not quite sure exactly of the thrust of your question.

Chairman STARK. It's just a question. I'll get to it in a minute if Mr. Wolff would like to indicate the size of his department's budget.

Mr. WOLFF. Mr. Chairman, I really don't know the size of my department's budget. I'm not the head of the department. I can get——

Chairman STARK. You can make a guess. How many people in your department, Mr. Wolff?

Mr. WOLFF. I am in the department of Federal legislation. There are five professional staff and two secretaries. But, of course, we also have a substantial travel budget. I would have to get back to you concerning my department's total budget.

Chairman STARK. Would you guess it's in the, you know, in the tens of millions of dollars?

Mr. WOLFF. No, I would say it is not that large, but I really think——

Chairman STARK. Twenty?

Mr. WOLFF. No. I think it's lower, but I really would not like to make a guess at that.

Chairman STARK. I am concerned by some of the testimony, as I generally am.

On page 8, for example, Dr. McAfee, you suggest that if the Government were involved in practice guidelines, you say "physicians with historical justification would be suspicious that cost savings rather than quality would be the Government's consideration."

Could you cite to me any time, to your knowledge, in recent history, and I want to start from about 1967, that the Medicare system has ever put cost savings ahead of quality or cite one instance when that has ever been suggested?

Dr. MCAFEE. Mr. Chairman, in my remarks before, I made reference to two programs that I have had intermittent involvement with in Maine. They both were Federal programs and they came——

Chairman STARK. Medicare programs?

Dr. MCAFEE. I make reference first to the PSRO program which had great difficulty in my State, even though there was a great deal of cooperation by physicians, and I served on the advisory board of my PSRO organizations. I traveled this country asking

other physicians to participate in this program because it was our attempt to create some standards that could be utilized in an appropriate clinical fashion to upgrade and maintain the quality of care in this country.

What we found, however, sir, was a continuing lack of support by the PSRO program for quality initiatives. I think that we made some significant efforts in quality. But they were efforts that were not proportional, at least in somebody's eyes, to the dollars that were spent in that program.

I would also point out, Mr. Chairman, that I did serve on my Regional Southwestern Maine Comprehensive Planning Group. I also served on my certificate of need committee in my State. I spent many volunteer hours in both of those endeavors.

I will tell you that because of the concern over dollars, the quality of care in Maine is significantly less than it could have been.

Chairman STARK. That was your concern.

Dr. MCAFEE. That continues to be my concern.

Chairman STARK. To save money at the expense of quality, is that what you're suggesting?

Dr. MCAFEE. Exactly so. I can remember one——

Chairman STARK. That's not the Federal Government's concern?

Dr. MCAFEE. No. Health planning was a Federal program, sir.

Chairman STARK. Administered by whom, Dr. McAfee?

Dr. MCAFEE. This was the certificate of need program which was a combined program between the Federal Government and——

Chairman STARK. And the State of Maine.

Dr. MCAFEE. And the State of Maine.

Chairman STARK. The certificate of need program, to suggest that that is cost savings rather than quality, if that is your concern, seems to me to beg the question. These were certificate of need programs that were to cut down wasteful expenditures, and I do not think there was ever any direction that you can cite that suggested that the Federal Government even for 1 minute would compromise quality for cost. And I take offense.

Let me go back and ask you, for example, if you will recall—were you in practice in 1967?

Dr. MCAFEE. I began practice in 1965.

Chairman STARK. Then you were aware of the Surgeon General's report at that time relating to smoking?

Dr. MCAFEE. Yes, sir.

Chairman STARK. Now, are you aware that the American Medical Association opposed that report and suborned it in exchange for getting votes from tobacco State Congressmen against Medicare? Are you aware of that, Doctor?

Dr. MCAFEE. Mr. Stark, I served at that time on the board of the American Cancer Society. My seat-mate was Surgeon General Terry. I will assure you that the majority of physicians in this country wholeheartedly endorsed that——

Chairman STARK. I am talking about the American Medical Association. The majority of physicians in this country do not belong to the American Medical Association. But I just wanted to suggest to you that the American Medical Association was suborning the warning that cigarettes could cause cancer in exchange for votes from tobacco State Congressmen.

I wonder if that is a record, Doctor, on which you would like to suggest that the Government is the one, indeed, who ought to be concerned about not—you ought to be suspicious of our means of supporting quality, but whether it is the AMA's? What do you think about a record like that? Are you proud of that?

Dr. McAfee. Mr. Stark, having devoted a great deal of my life to the antismoking effort and being involved in a specialty in which every one of my patients is subjected to a significant harangue from me or I will not take care of them if they smoke, I am proud of some of the accomplishments of organized medicine concerning smoking. We did accept tobacco advertising in our journals until 1952. Then in 1952, when we published the very first article identifying the link between cigarette smoking and cancer of the lung, we ceased taking advertising revenue from tobacco companies because we thought it was inappropriate. We have continued to conduct a very vigorous antismoking campaign, including supporting bills concerning cigarette advertising, particularly as it involves children and smoking in this country.

Chairman Stark. You come a little late to the table, Doctor. I just want to suggest that we are on page 7. You suggest—and to me it is audacious on its face—that we should suggest amending this bill to specify that some of the research grants should be provided to a national medical association such as the AMA with their record for complete indifference to the health care—for their indifference to anything but the pocketbooks of the physicians of this country, I think is an affront to the Federal Government.

And to suggest that on the other hand, the Federal Government disregards quality, as you do on page 8, to me is obscene. And I hope that you will stop what has been the practice of the AMA time and time again that any time anybody suggests that perhaps there is a link between efficient spending and expenditures and good quality care, that all the Federal Government is trying to do is come down hard on quality. I think that is an affront, and I do not think it serves those honorable physicians who disregard the AMA's statement. I do not think it serves them well.

I am sorry that it is necessary to always have the AMA in here pandering this kind of propaganda, because I do not think it serves the other witnesses who do good work. I am sure they will be back time and time again. But as long as they spend more in defeating a couple of members of this committee in political expenditures than they spend on quality assurance, I think you have seen the answer right there, and that is exactly what they have done.

So you have a record you serve a committee that spends more money on wasteful political expenditures, certainly useless ones, than they do on quality assurance. And I think that record speaks right for itself, and I just want to make sure that that is publicly known. So much for the AMA's concern for quality.

I want to thank very much the rest of the panel for their usual concern for the health care of people in this country and move on now, if we can, to the next panel. Thank you very much.

Chairman Stark. Our third panel will consist of Dr. Richard Wilbur, the executive vice president of the Council of Medical Specialty Societies, Lake Forest; Dr. Dennis O'Leary, the president of the Joint Commission on Accreditation of Healthcare Organiza-

tions; and Dr. Richard Cooper from my natal town of Milwaukee, WI, who is dean of the Medical College of Wisconsin.

I would recognize at this point Mr. Moody.

Mr. MOODY. Let me just say what a pleasure it is to have Buz Cooper with us, Mr. Chairman. He has been a major force in our community to find solutions to tough problems in a cost-effective and intelligent way in the medical field. I know he is going to make a valuable contribution today, and we are happy to have him here.

Chairman STARK. Gentlemen, your prepared testimony will appear in the record in its entirety. If you would like to expand on your testimony or paraphrase it or add to it in any way, please feel free to do so. We will start with Dr. Wilbur.

STATEMENT OF RICHARD S. WILBUR, M.D., EXECUTIVE VICE PRESIDENT, COUNCIL OF MEDICAL SPECIALTY SOCIETIES, LAKE FOREST, IL, ACCOMPANIED BY JAMES N. SUSSEX, M.D., PRESIDENT OF CMSS

Dr. WILBUR. Thank you, Mr. Chairman, members of the committee.

I am Dr. Richard Wilbur, executive vice president of the CMSS, and with me is Dr. James Sussex, the president of the CMSS and past president of the American Board of Psychiatry and Neurology.

CMSS, which represents the specialty societies in this country with some 300,000 members and——

Chairman STARK. Doctor, like the AMA, the electronics in this room has not come into the 20th century yet. If you could pull that microphone really close—no, that one in front of you is OK, but you almost have to swallow it. Thanks.

Dr. WILBUR. To continue, these are scientific and educational organizations whose very reason for being has been to teach their members how best to practice their specialty. Therefore, specialty medicine applauds the concept of the bill that you and Mr. Gradison have presented to us which states that it is to promote the use of the most appropriate and effective medical treatment.

The focus of this bill is on what is being purchased, not just the details of how it is going to be paid for. We certainly feel it is proper not to worry about how to pay the right amount for a procedure that should not have been performed in the first place. Along these lines, the specialty societies' interest in quality has led to their developing guidelines over the years. There have already been proven successes: The anesthesiologists with their monitoring which has led to a decrease in the number of anoxic deaths; the College of Physicians' 15 years of work with their Clinical Efficiency Assessment Project; the American Psychiatric Association in its recent guideline.

Much more, however, needs to be done. To this end, CMSS has recently had a standards conference in September 1987. At that time, we said it was the duty of specialty societies to set guidelines. Since then, they have been active. We have been working with Dr. David Eddy of Duke, who has developed a manual, now in its draft stages, which we intend to approve at a July 14 meeting. His efforts are to guide specialty societies in setting their own guidelines.

To summarize the 150 pages rapidly, he advocates that we look at the literature, the outcomes from good experiments; the specialty societies then develop a consensus by expert practitioners, academic and clinical alike, as to what is medically best because there is in our minds no substitute in evaluation of practice for the clinical knowledge, judgment, and insight of those who practice the art and science of medicine.

But at that point, we feel that when there are professionally developed guidelines, then value judgments have to be made by the prudent purchasers of the United States, Government and private alike. We believe the professional need to develop guidelines can be brought to you as a prudent purchaser, and we can tell you that for a certain amount of money, a certain procedure will get a certain percentage of good result; that with a different procedure, the cost may be double or triple, and the increased number of good results may be relatively slight.

At the same time, we feel that the individual patient must be a part of this decisionmaking process. We should develop these guidelines and then bring them to the individual patient who can decide for herself, for instance, whether she wants the lumpectomy with radiation, with chemotherapy, with full information of what it means to her quality of life and what it means to the likelihood of success.

Our concern, then, with H.R. 1692 is not with the concept but with the use of a single methodology which to us looks to the past and to what was done—the good, the bad, and the indifferent. Whereas, we in the specialty societies are looking to the present and the future and as to what ought to be done, not what was done. And we would like to suggest that if guidelines are to be developed, at least both kinds should be. We are concerned about how these guidelines will be maintained. They have to be flexible. They have to be innovative, and they cannot lead to an increase in the cost of care, of which the fastest growing element, as we have heard Mr. Gradison tell us, is the administrative cost of medicine.

The specialty societies would like to help. They are ready to help. They are wanting to help provide their experience and expertise that they have used in the past. In turn, we would appreciate your help in supporting the specialty societies development of guidelines and involving professional medical associations and societies before the standards are disseminated, while they are still being developed, by including us as members of advisory councils and in other ways.

In brief, sir, we applaud the concept of the prudent purchasing. We support the development of guidelines for appropriate care which are professionally reliable and cost effective in implementation. We have worked on these. We want to work with Congress, HHS, and the purchasers further on these. And we look forward to working together in this laudable enterprise.

[The statement of Dr. Wilbur follows:]

STATEMENT OF THE COUNCIL OF MEDICAL SPECIALTY SOCIETIES
RICHARD S. WILBUR, M.D.

Mr. Chairman, members of the Subcommittee, I am Dr. Richard S. Wilbur, Executive Vice President of the Council of Medical Specialty Societies. With me is Dr. James N. Sussex, President of the CMSS and a Past President of the American Board of Psychiatry and Neurology. We thank you for the opportunity to present these remarks today.

The Council of Medical Specialty Societies (CMSS) is a not-for-profit, scientific and educational medical professional association located in Lake Forest, Illinois. Our members are the 24 national medical specialty societies listed in Attachment 1. These specialty societies represent U.S. medical specialists certified by Boards recognized by the American Board of Medical Specialties. The combined memberships of the 24 societies is presently in excess of 300,000 physicians nationwide.

The CMSS goals and purposes are:

- To confront issues in American medicine;
- To improve the quality of medical care in the United States; and,
- To foster excellence in the education of physicians.

CMSS and specialty medicine are, therefore, supportive of the concept of H.R. 1692, which has as its purpose "to create a research and education program which can assist the medical profession in promoting the use of the most appropriate and effective medical treatment where such knowledge exists or can be developed to improve such treatment." The goals of the legislation and those of the CMSS and its members in this regard are parallel.

The Council has a long history of interest in, and dedication to, fostering activities to improve the quality of medical care and medical education. CMSS is one of the five sponsors of the Accreditation Council for Graduate Medical Education and one of seven sponsors of the Accreditation Council for Continuing Medical Education. It has active programs in the areas of patient safety, health manpower, health care delivery and interspecialty cooperation. It serves as a forum for discussion and a clearinghouse for the sharing of information on issues of concern to specialty medicine. A more complete description of CMSS and its activities is contained in Attachment 1.

CMSS and the specialty societies also have a long history of interest in the use of guidelines to improve the quality of clinical practice and patient care. Recently, this interest has increased dramatically as a responsible response by the medical profession to (1) the public's demand for proof of quality in health care, (2) recognition of the need for cost containment, (3) a desire to understand geographic variation in patient care, and (4) the crisis in professional liability. In 1987, the CMSS sponsored a conference in Washington on the subject of standard setting. This meeting was the first held to address specifically the development, use, and application of clinical standards by specialty societies. It was attended by representatives of all 24 CMSS member societies. The meeting resulted in the following observations: (1) that purchasers of health care were beginning to demand proof of quality; (2) that data to permit the formulation of judgments about quality in medical care were increasingly becoming available; (3) that the development of judgments about quality of care without physician input was dangerous; and (4) that the specialty societies have a duty to assist in the shaping of guidelines to evaluate medical practice. A tangible result of the conference has been the rapidity with which the specialty societies have begun to actively develop clinical guidelines. A partial listing of the practice policies, guidelines, and standards of patient care presently available from the CMSS member societies is appended to this statement (see Attachment 2).

CMSS has also promoted new methodologies for developing clinical guidelines. On July 14th, the CMSS Task Force on Practice Policies will hold a meeting for representatives of the 24 societies to exchange information of a practical nature on the creation of practice policies and to comment on a draft "primer" or manual on developing practice policies. The draft primer was written by Dr. David M. Eddy of Duke University in collaboration with CMSS and with the support of the John A. Hartford Foundation, Inc., of New York. An important feature of Dr. Eddy's work is that policies are first derived on the basis of outcomes data published in the literature. They are then subjected to a clinical evaluation process by physician experts from the relevant society or societies. Finally, the guidelines are subjected to value judgments by both patients and purchasers to assure that they "make sense" in terms of cost-benefit and patient quality of life.

CMSS is, therefore, strongly supportive of the idea that funding be made available for studies to improve the ability of physicians to diagnose and treat their patients. There is no question of the present need to support research on the outcome, effectiveness, and appropriateness of medical care delivered under Medicare and other programs. Traditionally, new medical knowledge has come from reports published in the clinical literature and presented at clinical meetings of specialty societies. As new information is obtained, and the experiences of the clinical researchers is validated by others, medical practice evolves. Specific treatments and management approaches to patient illness become "accepted medical practice."

It is also true, however, that clinical research has not been synthesized in any systematic manner. Frankly, the methods to do that are only now being developed, by Dr. Eddy and others, and sufficient resources to support such endeavors have not previously been forthcoming. The development of and routine updating of practice policies is a very expensive and time-intensive undertaking. Guidelines require review and modification almost as soon as they are developed and disseminated. We therefore applaud the recognition of the need for research by the sponsors of the legislation, and the financial commitment it promises.

However, we wish to share with you a concern regarding methodology. H.R.1692 proposes that the principal data used in the development of guidelines be derived from a consolidation of past claims information. You well know the problem of timeliness, or rather the lack thereof, of such data. Claims from 1979 or 1981 or 1983 will not necessarily reflect the state of the medical art today. Furthermore, one cannot assume that what was done yesterday (in the aggregate) was effective or appropriate. Changes may have already occurred in medical practice to alter what was state-of-the-art only a few years ago. Claims data describe what was done in the past; they should not be used exclusively to guide what should be done in the future.

In light of the recent and dramatic development of new and improved diagnostic and therapeutic technologies, and a virtual explosion in the acquisition of new clinical knowledge, we would urge you to support the work already being done by the specialty societies in the development of guidelines. The traditional mission of these societies, colleges and academies has been physician education and the improvement of patient care. It is vital that these organizations be involved in the development of guidelines at the outset. There is simply no substitute in the evaluation of medical practices for the clinical knowledge, judgment, and insight of those physicians who daily practice the art and science of medicine.
Physician-developed guidelines are also more likely to be adopted and utilized by practitioners if they are created by their specialty societies and not by outside organizations.

Examples of the successful promulgation and adoption of standards by practitioners come from a number of specialties. The American Academy of Pediatrics has, for example, published standards of pediatric care since 1938. The American College of Physicians has done pioneering work in technology assessment; more recently, the College has developed a number of guidelines for use in assessing physician competence.

The American College of Radiology has a widely accepted program for accreditation of mammography centers, which affords radiologists the opportunity for peer review and evaluation of the mammography facility, including equipment, staff, and quality control. The program provides assurances to the public that qualified personnel perform and interpret mammograms, and that women receive optimum mammographic examinations with the lowest possible risk.

The American Society of Anesthesiologists has developed a number of standards, one of which is on minimal monitoring for patients undergoing anesthesia. In areas where these have been adopted, there appears to be a diminution in the number of brain anoxia incidents and deaths, and a reduction in the number of professional liability claims in anesthesia.

We are pleased to commend to you the considerable interest and experience of our member societies in the development and implementation of practice policies. We also stand ready to offer you the services of CMSS to identify organizations and individuals to serve on the Technical Advisory Groups that will undoubtedly be required. We would be delighted to serve as a member of the Advisory Council if that is deemed to be appropriate.

Thank you again for the opportunity to comment.

Attachments

COUNCIL OF MEDICAL SPECIALTY SOCIETIES

P.O. Box 70/Lake Forest, Illinois
(312) 295-3456

Member Organizations

AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY
AMERICAN ACADEMY OF DERMATOLOGY
AMERICAN ACADEMY OF FAMILY PHYSICIANS
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ACADEMY OF OTOLARYNGOLOGY—
HEAD & NECK SURGERY, INC.
AMERICAN ACADEMY OF PEDIATRICS
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
AMERICAN COLLEGE OF PHYSICIANS
AMERICAN COLLEGE OF PREVENTIVE MEDICINE
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN PSYCHIATRIC ASSOCIATION
AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS
AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS
SOCIETY OF NUCLEAR MEDICINE
SOCIETY OF THORACIC SURGEONS

HISTORY

The Council of Medical Specialty Societies (CMSS) was founded in 1965 as the Tri-College Council by the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Surgeons. It was established to provide an independent forum for the discussion by medical specialists of issues of mutual concern and national interest. In 1967, as other specialty societies joined, CMSS adopted its current name. Today, one specialty from each of the twenty-four major specialties with certifying boards sanctioned by the American Board of Medical Specialties are represented on CMSS. The aggregate active voting membership of the twenty-four member CMSS societies is over 300,000 physicians. The Council acquired full-time administrative staff in 1976.

PURPOSE

CMSS is a 501(c) (3) not-for-profit tax-exempt educational and scientific organization established to permit discussion, action and policy-making by specialty societies on national issues affecting the practice of medicine.

CMSS GOALS

- *To Confront Issues in American Medicine*
- *To Improve the Quality of Medical Care in the United States*
- *To Foster Excellence in the Education of Physicians*

ORGANIZATION

CMSS Assembly. The CMSS is governed by its assembly, which addresses issues and sets policy at meetings held three times each year. Representation on CMSS is proportional, with each society entitled to one voting representative for each 5,000 active members or fraction thereof. There are more than 70 such representatives in the assembly.

Board of Directors. Interim activities of CMSS are governed by a nine member Board of Directors, elected annually by the assembly. The Board of Directors consists of the President, President-Elect, Vice President, Secretary, Treasurer, and four Members-at-Large.

FUNDING

Funding for CMSS programs and activities is derived principally from annual dues, of a specified amount per active member, contributed by each society. Special projects may also receive funding from outside sources.

NATIONAL ACTIVITIES

CMSS participates in and provides representation to the:

- *Council for Medical Affairs (CFMA)*
- *Accreditation Council for Graduate Medical Education (ACGME)*
- *Accreditation Council for Continuing Medical Education (ACCME)*
- *American Board of Medical Specialties (ABMS)*
- *National Board of Medical Examiners (NBME)*
- *National Resident Matching Program (NRMP)*
- *International Medical Scholars Program (IMSP)*

COMMITTEES

In addition to the internal committees (Bylaws, Finance, Nominating), several other committees serve to implement the Council's objectives.

Medical Education

The Medical Education Committee studies and makes recommendations to the assembly regarding the development and implementation of policies in graduate and continuing medical education. As a sponsor of the Accreditation Council for Graduate Medical Education (ACGME), the Accreditation Council for Continuing Medical Education (ACCME), and the Council for Medical Affairs (CFMA), the CMSS is involved in establishing standards for residency training and the voluntary accreditation of graduate and continuing medical education programs. The Committee is charged to assist in implementing the CMSS objective of relating medical education to improved patient care. CMSS provides the staffing for ACCME.

Patient Safety

The Patient Safety Committee monitors new developments and trends in professional liability. Its chief aim is to work toward establishment of continuing education programs for all physicians in the area of patient safety. As an example, the CMSS National Patient Injury Prevention Program, established by a grant from the John A. Hartford Foundation, Inc., of New York, has identified and presented data on clinical problems in medical care delivery to member societies. Other programs address informed consent, medical records, and physician/patient communications.

Health Care Delivery

The Health Care Delivery Committee identifies and studies issues associated with the financing and delivery of health care services. The committee also coordinates special projects on health care cost containment, quality assurance, technology assessment, and the development of practice guidelines.

Interspecialty Cooperation

The interspecialty Cooperation Committee provides a forum for discussion of interspecialty interests and problems and for coordination of projects stimulated by those discussions.

Health Manpower

The Health Manpower Committee identifies, studies, and makes recommendations on pertinent national physician manpower studies, and on federal and state activities affecting specialty medicine. As such, it has established a repository of public and private sector efforts in physician and allied health manpower, particularly those of its member societies. Each CMSS society has identified manpower experts to assist the committee with its activities.

Attachment 2

PARTIAL LIST OF

PRACTICE POLICIES, GUIDELINES AND STANDARDS

OF PATIENT CARE

Available from CMSS Member Specialty Societies

1. **American Academy of Allergy and Immunology**

   Executive Committee Statements:

   - Tartrazine - 1977
   - Epinephrine Injection - 1977
   - Allergen Standardization - 1980
   - Use of Radioallergosorbent and IgE Tests in Practice -1980

   Statement on Resuscitative Equipment - 1981

   Skin Testing and Radioallergosorbent Testing (RAST) for Diagnosis of Specific Allergens Responsible for IgE-Mediated Diseases - 1983

   Position Statement on Carotid Body Resection - 1985

   Position Statement on Clinical Ecology - 1985

   Position Statement on Candidiasis Hypersensitivity Syndrome - 1985

   Adverse Effects and Complications of Treatment With Beta-Adrenergic Agonist Drugs - 1986

   Measurement of Circulating IgG and IgE Food-Immune Complexes - 1988

2. **American Academy of Dermatology**

   Report on Credentialing and Privileging - 1988

   Guidelines of Care for Acne Vulgaris - 1989

   Guidelines of Care for Liposuction - 1989

3. **American Academy of Otolaryngology—Head and Neck Surgery, Inc.**

   Policy Statements on:

   - Allergy Techniques - May, 1984
   - Cochlear Implants
   - Mammoplasty - April, 1982
   - Infant Hearing - July, 1982
   - Hearing Evaluation - July, 1982
   - Ambulatory Procedures - July, 1982 - Reaffirmed May, 1984
   - Allergy - October, 1982
   - Hearing Aids - July, 1982
   - Thyroidectomy - March, 1983
   - Uvulopalathopharyngoplasty - July, 1984
   - Implantable Hearing Aids - Adopted September, 1986

4. **American Academy of Ophthalmology**

   Minimum Criteria for Ophthalmic Care - 1985

   Comprehensive Adult Eye Evaluation Preferred Practice Pattern - 1988

   Primary Open-Angle Glaucoma Preferred Practice Pattern - 1989

5. **American Academy of Pediatrics**
   Policy Reference Guide, a Comprehensive Guide to AAP Policy Statements - 1988
   Guidelines for Prenatal Care - 2nd edition - 1988 (See also ACOG, #8)
   Guidelines for Preventive Health Care in Infants, Children and Adolescents - 1988

6. **American Academy of Physical Medicine and Rehabilitation**
   Sample Screening Criteria for Review of Admissions to Comprehensive Medical Rehabilitation Hospital/Units - 1980
   Examples of Physiatric Programs and Procedures - 1985
   Principles of Practice Standards - 1985
   Physiatrists' Guidelines for Services Rendered - 1985

7. **American Association of Neurological Surgeons**
   Neurosurgical Case Screening Guidelines - 1989

8. **American College of Obstetricians and Gynecologists**
   Quality Assurance in Obstetrics and Gynecology - 1989
   Standards for Obstetric-Gynecologic Services (7th Ed.) - 1989
   Technical Bulletins (127)
   Guidelines for Prenatal Care - 2nd edition - 1988 (See also AAP, #5)

9. **American College of Physicians**
   Guide for Adult Immunization - 1985
   Clinical Competence in the Use of Flexible Sigmoidoscopy for Screening Purposes
   Hospital Clinical Privileges, Guidelines for Procedures in Gastroenterology and Nephrology - 1988
   Clinical Efficacy Reports: - (Statement Summaries, 1978 to 1986)
      Cardiology (8)
      Endocrinology-Metabolism (5)
      Gastroenterolgy (8)
      Hematology-Oncology (2)
      Nephrology (1)
      Neurology (4)
      Pulmonary Disease (4)
      Rheumatology (3)
      Miscellaneous Diagnostic (2)
      Miscellaneous Therapeutic (5)

10. **American College of Preventive Medicine**
    Guide to Clinical Preventive Services, Report to the U.S. Preventive Services Task Force - May, 1989

11. **American College of Radiology**
    Criteria for Radiation Oncology in Multidisciplinary Cancer Management - 1981
    Quality Assurance Guide to Appropriateness in Patient Care Services - 1985
    Medical Radiation - A Guide to Good Practice - 1985
    ACR Policies Relating to Clinical Standards of Care: - 1989
       Diagnostic Radiology (22)

Radiation Oncology (5)
Professional Credentialing Criteria (17)

12. **American Psychatric Association**
Manual of Psychiatric Peer Review - 1985

13. **American Society of Anesthesiologists**
Statement on Regional Anesthesia - 1983
Statement on Invasive Monitoring in Anesthesiology - 1984
Guidelines for Patient Care in Anesthesiology - 1985
Guidelines for Critical Care in Anesthesiology - 1986
Standards for Basic Intra-Operative Monitoring - 1986
Position on Monitored Anesthesia Care - 1986
Basic Standards for Preanesthesia Care - 1987
Statement on Routine Preoperative Laboratory and Diagnostic Screening - 1987
Guidelines for Ambulatory Surgical Facilities - 1988
Standards for Conduction Anesthesia in Obstetrics - 1988
Standards for Postanesthesia Care - 1988

14. **American Society of Colon and Rectal Surgeons**
Indications for Colonoscopy - 1985

15. **American Urological Association**
Guidelines for Urologic Patient Care - 1987

16. **College of American Pathologists**
Standards for Laboratory Accreditation - 1988

17. **Society of Thoracic Surgeons**
Definition of Thoracic Surgery - 1986

The following societies are presently developing guidelines:

American Academy of Family Physicians
American Academy of Neurology
American Academy of Orthopaedic Surgeons
American College of Emergency Physicians
American Society of Colon and Rectal Surgeons
American Society of Plastic and Reconstructive Surgeons

For further information, please call L. Jack Carow III or Rebecca Rhine Gschwend, CMSS, P.O. Box 70, Lake Forest, IL 60045, 312/295-3456.

Chairman STARK. Dr. O'Leary.

STATEMENT OF DENNIS S. O'LEARY, M.D., PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, CHICAGO, IL

Dr. O'LEARY. Yes, Mr. Chairman. I am Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations. I appreciate the opportunity to summarize the views of the joint commission on H.R. 1692 which we have detailed in our written testimony.

The joint commission strongly supports the intent of this landmark legislation. At the same time, we would like to offer several specific suggestions that we believe would broaden the legislation's impact. We suggest that these three changes are essential in assuring that the intended objectives of this bill are fully realized.

Since 1986, the joint commission has been engaged in a major developmental initiative designed to convert our periodic accreditation process to an ongoing performance-based evaluation system. This experience, plus the preliminary work products that we have successfully developed, form the basis of our suggestions. First, the legislation should provide funding support for the development of outcome or performance measures as well as practice guidelines. Because of our clear responsibility as an external evaluator of hospitals, we have directed considerable attention to the development of clinical performance measures. We have placed emphasis upon the development of these measures because of our concern about the content and potential utility of existing data bases that in most instances had been constructed to address concerns other than the quality and appropriateness of patient care.

On the basis of our experience, we know that the development of sophisticated and relevant performance measures is feasible. At the same time, the development of performance measures is at least as challenging and daunting as the development of practice guidelines. This is a difficult, time-consuming, and expensive process. And while we are very pleased with the progress that we have achieved to date, there is still a long way to go. Most importantly, we believe that it is essential that others become involved in this developmental activity and are concerned that resource constraints may limit future progress.

The potential importance of properly developed performance measures cannot be overstated. The development of performance measures is complementary to the development of practice guidelines and, in fact, reinforces the latter activity. The creation of packages, indeed, of performance measures and practice guidelines provides a potentially powerful tool for constructively influencing the delivery of appropriate, cost-effective, high-quality patient care services. These packages would also clearly enhance the educational intent of this bill.

Sound performance measures are also essential in assuring that practice guidelines are actually applied and are used as well in evaluating how effectively practice guidelines are used. Absent the opportunity to monitor execution through the application of rele-

vant performance measures, there is a significant risk that the practice guidelines that are developed will exist in a vacuum.

Second, we believe that the legislation should articulate an emphasis on quality as well as appropriateness. We draw a partially artificial but nevertheless important distinction between appropriateness and quality. Appropriateness addresses the need for correct or right decisions in managing the care of patients. Quality addresses the effectiveness with which the right decisions are executed. Both are important. While the financial and other consequences of incorrect decisions are clear, the costs and adverse effects of disquality, though less easy to isolate, are just as consequential.

We accordingly suggest that the legislation's mandate for the development of practice guidelines include the address of both appropriateness and quality issues. The same stipulation should also apply to performance measures which, in our experience, can be properly crafted to focus on quality or appropriateness, or both.

Third, the legislation should, we believe, articulate an intended objective of creating a national data base on the appropriateness and quality of care. Although the use of claims data bases and other large data bases may be acceptable on an interim basis, the content of these data bases is not adequate to serve the long-term objectives of this legislation. These data bases are not user friendly, and our experience indicates that 50 percent of important performance measure data elements are not now captured by UB 82. What is ultimately needed is a user friendly data base that primarily focuses on appropriateness and quality of care, is credible to the medical community, and is of potential use to a variety of parties with legitimate needs. In this era of concerns about health care, we believe that such a data base will become a vital national resource. We suggest that appropriate performance measures constitute the logical vehicle for developing the content of this data base.

We appreciate the opportunity to offer these comments and suggestions, and we will be pleased to answer any questions. Thank you.

[The statement of Dr. O'Leary follows:]

STATEMENT

OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS

concerning

H.R. 1692, MEDICAL CARE QUALITY RESEARCH ACT OF 1989

before

THE SUBCOMMITTEE ON HEALTH
COMMITTEE ON WAYS AND MEANS

May 24, 1989

Mr. Chairman and members of the Committee, I am Dennis S. O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. We appreciate the opportunity to present our views on H.R. 1692, the Medical Care Quality Research Act of 1989. The Joint Commission is a not-for-profit organization which has a long and unique history in developing performance standards for health care institutions and in evaluating these organizations through a well-established accreditation process. Today, the Joint Commission accredits approximately 5400 hospitals (approximately 80% of the nation's hospital population) as well as 3200 non-hospital health care organizations, e.g., nursing homes. Given the historic role of the Joint Commission in positively influencing the quality of care provided in hospitals and other health care organizations and its specific responsibilities as an integral element of the Medicare/Medicaid hospital certification process, we believe it is particularly important that the Joint Commission's views be included in Congressional consideration of H.R. 1692.

The Joint Commission joins with others in its strong support for this timely and thoughtful legislative proposal. H.R. 1692 would represent a tangible investment in the research and education that is needed to assist the medical community in promoting efficacious and cost-effective patient care. As important, however, the legislation conveys a clear message to health care providers, other private sector interests, and the American public that the Congress is committed both to quality patient care and to the containment of escalating health care costs.

At the same time, we do wish to express a concern that the scope and design of the legislation, as presently written, may not be sufficient to assure that its desired objectives are eventually reached. Quality patient care involves a series of important dimensions that include timely access to needed services, sound clinical decisions appropriate to the needs of the patient, effective execution of the decisions made, continuity and coordination of care among practitioners and across health care settings, involvement of the patient and family in the care process, and assurance of a safe and supportive patient care environment. We acknowledge the existence of significant medical uncertainty concerning appropriate clinical practices and the resultant importance of research that leads to rational practice guidelines as the basis for sound decision-making. The direct financial consequences of the use of unneeded clinical services are clear. This, however, is not the only issue. The inadequacy of current efforts to systematically monitor the broader spectrum of patient care, particularly the effective carrying out of correct decisions, is also consequential. We submit that the potential costs of disquality, albeit less easy to isolate,

are of a magnitude at least as great as the costs of inappropriate decisions.

For the past three years, the Joint Commission has been engaged in a major developmental effort to address this critical issue. We are now in the process of converting to a performance-based evaluation system applicable to all major types of health care organizations. Integral to this effort is a major re-casting of our standards to emphasize those clinical and managerial functions that relate directly to quality care, the definition of performance measures related to patient outcomes and organizational function, and the eventual integration of outcome information into a performance-oriented database. On the basis of this intense experience, we would like to offer the following observations:

- Beyond the obvious issue of medical uncertainly, there is a striking paucity, indeed a virtual absence, of information concerning day-to-day routine clinical practice. Simply put, practitioners and organizations have not had the tools necessary to monitor what is done to and for patients on a daily basis. This is an increasingly compelling issue as advancing technology broadens the range and complexity of patient care and as the patient population itself ages and becomes more fragile and vulnerable.

- While the health services research opportunities and needs are many, the critical elements of a successful monitoring system are sound practice guidelines, sensitive and properly focused outcomes or performance measures, and an accessible database designed primarily to provide meaningful information concerning the quality and appropriateness of patient care. The translation of any initiative to improve the quality and appropriateness of care, whether undertaken by government or by the private sector, absolutely requires all three components.

It is these observations that form the basis of our concern about the scope and design of this legislation. In specific, the legislation does not appear to recognize and articulate the need for developmental efforts focused on the creation of useful outcome (performance) measures. We respectfully submit that such measures, now at a formative developmental stage in limited areas, are the central ingredient necessary to assure that the objectives of this legislation are achieved.

We would like to elaborate on the basic characteristics of outcome measures. For such measures, we use the generic term "indicators" which is intended to emphasize the primary importance of these measures as monitors of performance. Attached as Exhibit I to this statement are several sets of clinical indicators drafted by national expert consensus panels under the aegis of the Joint Commission. The Obstetrics Care and Anesthesia Care indicators are in the late stages of pilot testing and will be implemented in accredited hospitals in 1990. The Oncology Care and Trauma Care indicators, as well as Cardiovascular Care and certain Hospitalwide indicators, will enter pilot testing later this year, with implementation in hospitals targeted for 1991.

As is evident, indicators describe relatively precise measures of important aspects of care. We underline the following important characteristics of indicators:

- Indicators may be designed to examine either organizational or clinical performance. As such, they are potentially applicable, either directly or indirectly, to all of the dimensions of quality of care previously described.

- Under the heading of clinical care, specific indicators can measure quality or appropriateness or both.

- Clinical indicators are not clinical standards or practice guidelines. However, clinical indicators establish a clear need to define clinical expectations through the formulation of practice guidelines.

- A clincial indicator is usually not a single data element but rather consists of a composite of data elements designed to provide a clear description of the event to be measured and, often, the characteristics of the patient population for which such an event is of relevance.

- Clinical indicators can be designed to address a segment of clinical care (e.g., obstretrics), care in a specific type of health care setting (e.g., hospital, long term care facility), or a particular diagnosis or procedure.

- Clinical indicators may address longer-term outcomes, such as patient functional status, or more intermediate outcomes that are specific to health care settings. The latter often provides a basis for establishing specific practitioner or organization accountability.

- Certain indicators may focus on the process of care. This is appropriate when there is a scientific basis for believing that the care provided (or not provided) will lead to a specific patient outcome.

- Clinical indicators constitute an essential tool for assuring the broad, systematic and on-going review of patient care in a variety of health care settings.

In order to illustrate the nuances and complexities of indicator development, we provide as Exhibit II three Clinical Indicator Development Forms that respectively describe the formulation of specific indicators for induction of labor/Caesarian section, mortality following heart bypass surgery, and management of patients with head trauma. Beyond the clear precision of these indicators, we draw attention to the following:

- Definition of terms and linkage to precise ICD-9-CM codes is essential in assuring uniformity in the collection of data.

- The patient population addressed by an indicator may include important subcategories, as in the case of heart bypass surgery patients. Such information is not captured in claims databases.

- Interpretting the meaning of clinical indicator data requires not only frequency information (numerator data) but also careful characterization of the patient population being reviewed (denominator data). For example, for head trauma patients who experience delayed surgical intervention, the appropriate denominator is all trauma patients undergoing brain surgery, not all trauma patients or all patients treated in the emergency department. Attention to numerator and denominator definition is important because performance measures are often characterized as relative rates of occurrence.

- It is important to determine whether a clinical indicator is a relative rate indicator or rather identifies sentinel events (rare but serious adverse patient outcomes). Relative rate indicators are commonly subject to trend analysis or are used to isolate outliers; thresholds may be established to determine when more intensive review is indicated. By contrast, sentinel events are major untoward occurrences, such as rare deaths or uncommon significant functional impairment, which warrant investigation of each occurrence. For example, a certain level of post-operative coronary artery bypass mortality may be determined to be acceptable, but every maternal death requires evaluation.

- It is important to define the clinical issue that the indicator is designed to address. This establishes its potential utility and importance. For instance, the indicator for induction of labor or Caesarian section for non-clinical reasons is an index of appropriateness and focuses attention on the avoidance of unnecessary risk for the mother or the infant.

- Similarly, <u>what</u> the indicator is intended to measure must also be determined. A number of variables may be reflected in outcome data. Some of these are patient factors (e.g., severity-of-illness, comorbid conditions) that are not within the control of the practitioner or the health care organization. However, practitioner and organization performance variables <u>are</u> usually controllable and indeed are the object of a thorough monitoring process. Seemingly narrow indicators may in fact address a surprisingly broad scope of practitioner and/or organization performance variables. This is illustrated by the clinical indicator that addresses delayed surgical invention following head trauma.

- The sources of the indicator data elements must be identified. Key data are usually, but not always, available in the patient record. A potentially useful indicator may have no practical utility today because an important data element is not readily and consistently accessible for incorporation into the performance database. While

currently a constraint, this data availability problem will be solved incrementally by a growing awareness of the strong positive impact of good performance data.

Against this descriptive background of the characteristics and applications of performance measures, we would now like to examine the relationship of performance measures to what, we believe, should be the long-term objectives of this legislation. These include the following:

. The development of useful practice guidelines.

. The application of these guidelines in day-to-day practice.

. The creation of a complete and user-friendly database focused on the quality and appropriateness of care.

As we interpret the legislation, these objectives are well-articulated only in part. We display the relationships between performance measures and these objectives in Exhibit III and submit for your consideration the following analysis of these issues.

1. Practice guideline development. Practice guidelines are in essence statements of performance expectations. The legislation appears to place heavy emphasis upon the application of practice guidelines in addressing appropriateness of care issues, i.e., what are the right decisions. We suggest that practice guidelines also can and should be developed to address quality of care issues, i.e., are the right decisions effectively carried out. Performance measures provide data and information that serve as the basis for determining whether expectations are met. As previously stated, such measures can be designed to address appropriateness or quality or both.

   Given the modest amount of relevant information in the scientific clinical literature, both practice guideline development and performance measure development virtually require an approach that depends upon the use of expert consensus panels. The Joint Commission has had excellent success with this approach in developing performance measures over the past three years. Other organizations have enjoyed similiar success with this method in formulating practice guidelines.

   There is an obvious interplay between practice guideline and performance measure development. In our experience, expert panels rapidly gravitate to the key issues. And whether the question is "What patient care activities are important to measure?" or "For what patient care activities should expectations be defined?", the answer is usually the same. Not surprisingly, attention becomes appropriately focused on patient care services that are provided in high volume or are inherently risky.

   As a practical matter, practice guideline development may precede,

be concurrent with, or follow performance measure development. In its initial developmental work, the Joint Commission deliberately selected Obstetrics Care and Anesthesia Care because practice guidelines already existed in these disciplines. We have subsequently entered clinical areas where practice guidelines are incompletely formulated or absent. It is apparent that the development of a set of practice guidelines begs the need for relevant performance measures and that the converse is also true. We believe this is a healthy dynamic that constantly identifies areas where developmental work is needed. And, as a product of this dynamic, consider the positive impact on both cost and quality of a "package" of practice guidelines and performance measures addressed to a high volume costly clinical procedure.

Given the long-term objectives of this legislation, we would emphasize as well that relevant performance measures will be required in order to validate specific practice guidelines. For example, the validity of practice guidelines applicable to the surgical versus the medical management of patients with coronary artery disease can only be assessed through the use of accepted indicators that meassure clinical and functional patient outcomes. This consideration is particularly important in view of the continuing evolution of the art and science of medical practice. This will create an on-going need to update and re-formulate practice guidelines as well as performance measures over time.

We comment finally on the educational objectives of this legislation. While dissemination of practice guidelines to the medical community is an important activity which we strongly support, we suggest that this activity alone may not be sufficient to achieve the desired practitioner behavior and practice changes that are the target of the educational initiative. Here too, performance measures and the resulting data may play an important role in meeting the objective. In our experience, the feedback of credible performance data to individual practitioners is a powerful educational and behavior-altering tool. We note that the feedback of performance data to practitioners was probably the single most important factor underlying the success of the Maine Medical Assessment Project.

2. Practice guideline execution. The selection and development of state-of-the-art practice guidelines is only a first-stage effort. Guidelines must eventually be applied, and performance must be measured and evaluated in relation to the guidelines. Valid performance measures are essential in achieving this objective. Absent this application, practice guidelines will exist in a vacuum.
A performance evaluation system based on well-conceived indicators can serve to monitor and reinforce the use of practice guidelines. As noted earlier, measures of clinical process are appropriate when the process has been shown to correlate with patient outcomes.

Practice guidelines are often built on such research and can be incorporated directly into a performance monitoring system using process indicators.

As a further example, outcome measures may be used as screens to identify instances in which practice guidelines have not been effectively used. For instance, an unusually low complication frequency may imply that the procedure is being performed when it is unnecessary. Conversely, execessive mortality for a particular procedure may result from the use of a high-risk approach to care when a less risky alternative was available (and identified in practice guidelines applicable to such patients).

Thus, performance measures can then be used to monitor the proper execution of practice guidelines. We believe that this execution of practice guidelines is in fact a fundamental objective of the proposed legislation.

We note that the ability to assure effective application of practice guidelines is somewhat dependent upon setting of care. But certainly within organizational settings, where most of the high-volume, high-risk services are provided, there is ample potential leverage through the accreditation process and regulatory requirements to assure that practice guidelines and performance measures are properly applied.

3. Database development. The legislation appears to place emphasis upon the use of claims databases and other existing large databases to further the legislative intent. We acknowledge that this interim approach may be acceptable and indeed necessary. However, claims databases were developed and are used primarily for purposes not related to the appropriateness and quality of care. And other databases, while often voluminous in content, contain a spectrum of data elements whose relationship to the appropriateness and quality of care has not been established. In addition, important data elements that are critical to performance evaluation may not be routinely collected in these databases. This is a vital consideration where composites of data elements (as in the case of clinical indicators) as opposed to individual data elements provide the most sensitive measures of performance. Finally, while we applaud the ingenuity of certain researchers in successfully extracting useful quality and appropriateness information from claims databases, it is obvious that these databases are not user-friendly. For these reasons, we suggest a more visionary approach to database development and use.

What is needed is a national database whose content and applications are primarily oriented to the appropriateness and quality of patient care. We draw attention to a parallel example--the national data bank on practitioners that is being created as a component of the Health Care Quality Improvement Act. The content of an appropriateness

and quality database should be built around carefully formulated practice guidelines and performance measures, such as the clinical indicators now being developed by the Joint Commission and others. This would assure the availability of appropriateness and quality performance data that is both understandable and potentially useful to various parties that have legitimate needs for this information.

A commitment to this type of database would set the stage for addressing important related issues. These include the need for uniform definitions of data elements, the practical and economic feasibility of data collection, and methods for validating and assuring data accuracy. These are issues that plague current databases and ones that must be resolved in order to assure the utility of and confidence in future databases. A functional database will eventually provide the capability to monitor the effectiveness of practice guidelines and will make available the information necessary to permit future updating and refinement of practice guidelines.

The Joint Commission already has an extensive database containing standards compliance information for over 8000 provider organizations. We plan to enhance this database with the type of quality and appropriateness performance information described above. In doing so, we make no presumption as to the future locus, content, and uses of similar databases, but we do intend to incorporate performance information into our national accreditation process.

In this statement, we attempt to make a simple point in a detailed fashion. Performance measures are themselves important. Like practice guideline development, the development of meaningful and useful performance measures is a long, arduous and expensive process. But it is vital.

In fact, the development of <u>both</u> guidelines and indicators is essential to rational improvement in patient care and, as emphasized above, is self-reinforcing. The potential importance of coordinated development of guideline and indicator packages and the evolution of a national performance database cannot be overstated.

The Joint Commission has already sponsored two national invitational conferences on clinical indicator development, each of which was attended by representatives from over 100 professional societies and organizations, many of whom are also involved in practice guideline development. Conference participants have fully recognized the importance and the challenge of this activity; they have also expressed concern about the expense in involved, thus reinforcing the need for the type of funding contemplated by this legislation.

The Joint Commission does not have, nor does it wish to have, a corner on the market of performance measure development. What we do have is in-depth experience that serves as a basis for understanding what needs to be done. Later this year, the Joint Commission intends to publish a Primer on Clinical

Indicator Development. This Primer will facilitate the development of performance measures by other national organizations and indeed by individual health care organizations. However, these activities may be constrained if external funding is not available.

In summary, the Joint Commission respectfully suggests the following modifications to this proposed legislation.

1. The legislation should recognize the importance of and need for the development of performance measures and should accordingly assure the availability of funding to support the development of both practice guidelines and performance measures.

2. The legislation should emphasize the importance of addressing both appropriateness and quality issues through the formulation of practice guidelines and performance measures.

3. The legislation should articulate an intended objective of creating a national database on the appropriateness and quality of care.

We respectfully submit that these changes are essential in assuring that the federal dollars to be spent on this initiative are productively invested and that the objectives of this legislation are fully realized. All parties with a stake in this arena must bear in mind that the ultimate goal is timely patient access to appropriate, cost-effective, high quality care. The development of practice guidelines, performance measures, and databases are but a means to that end.

Thank you for providing me the opportunity to present the views of the Joint Commission on this important legislative initiative. I am prepared to respond to any questions you may have.

EXHIBIT I

Joint Commission

POTENTIAL CLINICAL INDICATORS
FOR PILOT TESTING

As one important component of the Joint Commission's Agenda for Change, expert task forces worked in 1987 to identify clinical indicators for subsequent pilot testing. The following three lists of indicators for hospitalwide, anesthesia and obstetrical care are the product of this first phase of the task forces' work.

Seventeen hospitals will work closely with the Joint Commission for the next several months to test the utility and feasibility of these indicators and the related covariates (risk factors) also noted on the attached lists. Pilot test results will be reviewed by the expert panels in 1988 as a guide to improving the indicators where necessary.

Each indicator and covariate is actually composed from multiple data elements that will be collected from hospital records and transmitted to the Joint Commission. Validity and reliability of data will be supported by abstraction forms, coding manuals, and glossaries precisely defining each data element. The next draft of these materials will emerge from the combined efforts of Joint Commission staff, clinical task force members, and pilot site hospitals.

In their current form, many of the clinical indicators deliberately exclude specific temporal, procedural or diagnostic references. For example anesthesia care indicator #4 concerns peripheral neurologic deficits following adminstration of an anesthetic. The precise time period of interest when tracking this occurrence will not be defined until field testing is completed. Thus, the indicators as later refined will be a desirable amalgam of professional judgment and empirical analysis.

It is important to recognize that these clinical indicators, either singly or in aggregate, are not sufficiently precise to be direct measures of quality. They may prove to be tools which hospitals can use to identify areas of clinical care that warrant closer evaluation. For the Joint Commission they may be helpful when used in concert with the revised standards and ennanced survey processes which are also under development. Initial answers to these questions will receive concerted attention during the pilot test described above and will be refined in subsequent phases of the Agenda for Change developmental activities.

March, 1988

Joint Commission

POTENTIAL HOSPITALWIDE CLINICAL INDICATORS

1. Unplanned readmissions to a hospital shortly after in-patient surgery.

2. Unplanned admissions to a hospital shortly after out-patient surgery or specified procedures.

3. Development or worsening of pressure ulcers (decubiti).

4. Development of wound infections after clean or clean-contaminated surgical procedures.

5. Development of pneumonia in patients treated in special care units.

6. Development of infections related to the use of intravascular devices in special care units.

7. Proper timing of antibiotic prophylaxis for specified surgical procedures.

8. Appropriate use of blood culture sensitivities in the treatment of bacterial sepsis.

9. Development of complications associated with sub-optimal methods of administration and monitoring of specified medications.

10. Commission of important medication errors resulting in death or major morbidity.

11. Mortality of patients with specified medical conditions either during hospitalization or within thirty days of admission if death occurs at another institution to which the patient was transferred.

12. Mortality of patients after specified surgical procedures either during hospitalization or within thirty days of admission if death occurs at another institution to which the patient was transferred.

13. Mortality among patients treated in the hospital for injuries sustained immediately prior to treatment when death occurs within thirty days of injury or during a hospitalization that was precipitated by the occurrence of the injury.

March, 1988

Covariates

- Age
- Sex
- Height and weight
- Braden Scale (Risk Predictors for Skin Breakdown) on admission to hospital and special care units
- Glasgow Coma Score on admission to hospital and special care units
- Trauma Score of patients prior to treatment for injuries
- Diagnoses on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units
- Types of surgical or other specified procedures, if any
- Nature of surgical or other specified procedures, if any (scheduled, urgent, or unscheduled)
- Type and site of intravascular devices used in special care unit
- Selected chronic medications on admission to hospital
- Selected laboratory values on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units
- Temperature, pulse, respiration, and blood pressure on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units

Other information

- For patient admitted after out-patient procedure: stated reason for admission
- Insertion of drains during clean and clean-contaminated surgery
- Patient with endotracheal tube or tracheostomy in special care unit
- Use of nasogastric tube in special care unit

Joint Commission

POTENTIAL ANESTHESIA CARE CLINICAL INDICATORS

1. Mortality within a specified time* following anesthesia care.

2. Failure to emerge from general anesthesia within a specified time.

3. Development of injury to the brain or spinal cord within a specified time following anesthesia care.

4. Development of a peripheral neurologic deficit within a specified time following anesthesia care.

5. Cardiac arrest within a specified time following anesthesia care.

6. Clinically apparent acute myocardial infarction within a specified time following anesthesia care.

7. Fulminant pulmonary edema within a specified time following anesthesia care.

8. Respiratory arrest within a specified time following anesthesia care.

9. Aspiration of gastric contents with development of typical x-ray findings of aspiration pneumonitis within a specified time following anesthesia care.

10. Development of post dural puncture headache within a specified time following anesthesia care.

11. Dental injury during anesthesia care.

12. Ocular injury during anesthesia care.

13. Unplanned hospital admission within a specified time following an outpatient procedure involving anesthesia.

14. Unplanned admission to an intensive care unit within a specified time following administration of an anesthetic.

* All time ranges will be specified following evaluation and analysis of pilot site empirical data.

March, 1988

Covariates

- Age
- Sex
- Height
- Weight
- Pregnancy status including gestational age, if pregnant
- ASA class including emergency status
- Pre-anesthetic diagnoses
- Type of operative procedure
- Duration of operative procedure

Other Information

- Time and place of procedure
- Personnel support for procedure
- Type of anesthetic
- For patients admitted after out-patient procedure, stated reason for admission

March, 1988

Joint Commission

POTENTIAL OBSTETRICAL CARE CLINICAL INDICATORS

1. The induction of labor for indications other than diabetes, premature rupture of membranes, pregnancy induced hypertension, post-term gestation, intra-uterine growth retardation, cardiac disease, isoimmunization, fetal demise, or chorioamnionitis with or without a cesarean section.

2. A primary cesarean section for failure to progress.

3. A successful or failed vaginal birth after cesarean section (VBAC).

4. The delivery of an infant by planned repeat cesarean section weighing less than 2500 gms or with hyaline membrane disease.

5. The delivery of an infant following the induction of labor weighing less than 2500 gms or with hyaline membrane disease.

6. Eclampsia.

7. The in-hospital initiation of antibiotics 24 hours or more after a term vaginal delivery.

8. Excessive maternal blood loss except with abruptio placenta or placenta previa as evidenced by either a red cell transfusion, a hematocrit less than 22 or a hemoglobin less than 7, or a decrease in hematocrit of more than 11 or of hemoglobin more than 3.5.

9. A maternal length of stay more than 5 days after a vaginal delivery or more than 7 days after a cesarean section.

10. A maternal re-admission within 14 days of delivery.

11. A maternal death up to and including 42 days postpartum.

12. The in-hospital intrapartum death of a fetus weighing 500 gms or more.

13. The perinatal death of an infant weighing 500 gms or more.

14. The neonatal death of an infant with a birthweight of 750-999 gms born in a hospital with an NICU.

March, 1988

15. The delivery of an infant weighing less than 1800 gms in a hospital without an NICU.

16. The transfer of a neonate to an NICU at another hospital.

17. A term infant admitted to an NICU.

18. An Apgar score of 3 or less at 5 minutes.

19. The diagnosis of massive aspiration syndrome referenced as ICD9-CM code 770.1.

20. The diagnosis of birth trauma referenced as ICD9-CM code 767.

21. A term infant having a clinically apparent seizure prior to discharge from the delivery hospital.

Covariates

Infant birthweight

Additional information

Admission diagnoses on maternal readmission
Parity and gravidity
Infant birth order (for multiple births)
Principal diagnosis in cases of fetal death

March, 1988

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ONCOLOGY INDICATORS SUMMARY LIST

G-D1: Surgical pathology consultation reports containing histological type, AJCC/pTNM classification, tumor size, status of margins, appropriate lymph node examination, and assessment of invasion or extension as indicated, for patients with resection for primary cancer of the lung, colon/rectum or female breast.

G-D2: Discrepancy between intra-operative surgical pathology consultation on frozen section/smear and final surgical pathology report for patients with primary cancer of the lung, colon/rectum or female breast.

G-D3: Patients undergoing treatment for primary cancer of the lung, colon/rectum or female breast without AJCC pathologic stage of tumor designated by treating physician.

G-D4: Absence of a written pathology report in the medical record documenting the pathologic diagnosis of patients treated for cancer of the lung, colon/rectum or female breast.

G-T1: Death or hospitalization of patients due to complications related to adjuvant therapy for primary colorectal or female breast cancer.

G-T2: Systematic assessment and management of pain for all hospitalized patients with pain due to metastatic cancer of the lung, colon/rectum or female breast.

G-F1: Survival of patients with cancer of the lung, colon/rectum or female breast by stage and histologic type.

B-D1: Absence of estrogen receptor diagnostic analysis in female patients with invasive primary breast cancer for tumors larger than one centimeter in greatest dimension.

B-D2: Absence of documented AJCC clinical staging in medical record prior to first course of therapy for female patients with primary breast cancer.

B-T1: Female patients with AJCC pathological Stage II lymph node positive primary invasive breast cancers not treated with systemic adjuvant therapy.

B-T2: Treatment of female patients with primary invasive AJCC clinical stage I or II female breast cancer by excisional biopsy, segmental mastectomy, or quadrantectomy without radiation therapy.

L-D1: Patients with serious complications resulting from mediastinoscopy or trans-thoracic needle biopsy for possible and/or confirmed diagnosis of primary lung cancer.

L-D2: Thoracotomies without resection of tumor in patients with non-small cell primary lung cancer.

L-T1: Surgical complications of pulmonary resection for patients with primary lung cancer including empyema, broncho-pleural fistula, post-operative atelectasis requiring bronchoscopy, reoperation for post-operative bleeding, persistent requirement for mechanical ventilation greater than 5 days post-op, readmission within 7 days of discharge, or death.

C/R-D1: Operative report on patients with resection of primary colorectal cancer lacking documentation of location of primary tumor within the large intestine, local extent of disease, extent of resection and assessment for residual disease in abdomen by vision, palpation, or biopsy including liver and additional colonic primaries.

C/R-D2: Adequate pre-operative evaluation by attending physician for patients with primary colorectal cancer to include examination of the entire colon, liver function tests, chest x-ray, and CEA levels.

C/R-T1: Documentation of referral to or consultation by a radiation oncologist for patients with primary rectal cancer stage II or greater.

C/R-T2: Patients with primary rectal cancer undergoing abdominoperineal resections with 8 cm. or more of free distal surgical margin present on specimen as documented in surgical pathology gross description.

DRAFT

TRAUMA INDICATORS SUMMARY LIST

1(PH): Trauma patient with prehospital emergency medical services (EMS) scene time greater than 20 minutes.

2(PH): Copy of ambulance run report(s) not present in ED medical record for trauma patient transported by prehospital emergency medical services (EMS) personnel.

3(ED): Absence of initial and hourly sequential documentation in ED record of physiologic measurements for trauma patient from ED arrival until admission to OR, ICU, transfer to another institution, or death, includes all phases of ED evaluaiton and care, regardless of physical location of patient.

4(ED): Comatose trauma patient leaving ED prior to establishment of a mechanical airway.

5(ED): Trauma patient, with altered state of consciousness upon ED arrival, receiving initial head CT scan greater than 2 hours after ED arrival.

6(ED): Trauma patient with diagnosis of epidural or subdural brain hematoma receiving craniotomy greater than 4 hours after ED arrival (excluding ICP monitoring).

7(ED): Absence of initial and hourly sequential documentation in ED record of neurologic status measurements for trauma patient with diagnosis of skull fracture, intracranial injury and/or spinal cord injury.

8(ED): Trauma patient with discharge diagnosis of cervical spine injury not indicated in admission diagnosis.

9(ED): Death of trauma patient with discharge diagnosis of closed pelvic fracture and transfusion of greater than 6 units of blood.

10(ED): Interval of greater than 8 hours between ED arrival and initial OR treatment for trauma patient with open fracture of tibia resulting from blunt trauma.

11(ED): Trauma patient with diagnosis of liver or splenic lacerations receiving laparotomy greater than 2 hours after ED arrival (excludes patients who do not require surgery).

12(ED): Trauma patient with gunshot wound or stab wound which penetrates the abdominal cavity not receiving laparotomy.

13(ED): Trauma patient receiving initial abdominal, thoracic, vascular (excluding orthopedic, plastic, and hand surgery), or cranial surgery more than 24 hours after ED arrival.

14(ED): Trauma patient transferred to another acute care health care facility greater than 6 hours after ED arrival in the initial hospital.

15(ED/OR): Transfusion of platelets and/or fresh frozen plasma within 24 hours of ED arrival in adult trauma patient receiving less than 8 units of packed RBCs or whole blood.

16(OR/ICU): Return of trauma patient to OR within 48 hours of completion of initial surgery.

17(OR/ICU): Non-fixation technique of femoral diaphyseal fracture for adult trauma patient.

18(GENERAL): Trauma patient with isolated femoral diaphyseal fracture not receiving physical therapy (PT) or rehabilitation therapy (RT).

19(GENERAL): Deaths of patients with one or more of the following conditions who did not receive surgery for the condition: tension pneumothorax, hemaperitoneum > 1000 cc, hemothoraces > 1000 cc, ruptured aorta, retro-peritoneal and pelvic hematoma, pericardial tamponade, and intracranial hematoma subcategorized by patients who arrive at the admitting hospital directly from the scene of trauma and those who are received by transfer from a referring health care facility.

20(GENERAL): Percent of autopsies for trauma patients dying within 48 hours of ED arrival.

EXHIBIT II

1

CLINICAL INDICATOR DEVELOPMENT FORM

I INDICATOR

OB-1: The induction of labor with and without a cesarean section for indications other than diabetes, premature rupture of membranes, pregnancy induced hypertension, post-term gestation, intra-uterine growth retardation, cardiac disease, isoimmunization, fetal demise, or chorioamnionitis.

II DEFINITION OF TERMS

A) Terms related to data elements or sources of information.

Induction of labor: initiation of labor by extraneous means through the use of uterine contraction stimulating agents (Pitocin, castor oil, prostaglandins) or documented artificial rupture of the membranes prior to onset of spontaneous contractions. 73.4, 73.01, 73.1

Indicated conditions: as defined by ICD-9-CM codes: diabetes mellitus 648.0- (250.--); premature rupture of the membranes 658.1-; hypertension 642.-- (760.0); gestation 645.0-; intrauterine growth retardation 656.5-; cardiac disease 648.6- (391.-, 398.-); isoimmunization 773.0, 773.1, 773.2 (656.2-); fetal demise 656.4-; chorioamnionitis 658.4-, 762.7.

B) Indicator Population Analytic Criteria

1) Subcategories: None

2) Numerator(s): Patients induced without above indications.

3) Denominator(s): Patient inductions

4) Other:

DRAFT

III **RATIONALE**

A. Please explain why this indicator would be useful to assess and specify the process or outcome that would be monitored.

Induction of labor for non-medical reasons may place the mother and infant at risk for morbidity/mortality. High rates of elective induction may increase the likelihood of adverse patient outcomes (i.e., unnecessary cesarean sections or the potential of premature delivery). Higher rates when compared to peer institutions may indicate less appropriate care.

B. Please list the aspects of quality and/or appropriateness of patient care that would be assessed by this indicator.

1. Judgement of the attending physician/certified nurse midwife.

DRAFT

IV DATA SOURCES

Please identify the source of documentation from those listed in Appendix A (e.g., anesthesia report) for each data element listed on the left.

Data Elements	Data Source/Document (ICD-9-CM
1. induction 73.4, 73.01, 73.1	a. face sheet codes)
	Labor &
	b. delivery record
	c. operative report
2. principal & secondary discharge diagnoses	a. facesheet(s)
	b.
	c.
3. C-section excludes ICD-9-CM codes 74.- category	a. face sheet
	b. operative report
	c.
4.	a.
	b.
	c.
5.	a.
	b.
	c.

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V. INDICATOR EVALUATION

A. Does this indicator identify sentinel events (all occurrences warrant investigation) or is this a relative rate indicator (further assessment occurs if institution shows trend or is a statistical outlier compared to peers)?

Circle One: Sentinel Event Relative Rate

1) If relative rate, are there currently recognized acceptable rates of occurrence? Yes ___ (Acceptable Rate ___ %) No X

If yes, what is the source for this rate?

	Specific Reference
Research Literature	_____
Professional Guidelines	_____
Textbooks	_____
Other	should be relatively uncommon

2) Are there existing databases from which indicator occurrence rates and/or institutional variance may be established/ verified? Yes ____ No X

If yes, please list the databases and their location.

Databases	Location
a. _____	_____
b. _____	_____
c. _____	_____
d. _____	_____

B. Please rate the importance of each aspect of care listed in III B relative to indicator activity.

		Somewhat Important	Important	Very Important	Essential
Aspect 1	X	1	2	3	**4**
Aspect 2	_____	1	2	3	4
Aspect 3	_____	1	2	3	4
Aspect 4	_____	1	2	3	4
Aspect 5	_____	1	2	3	4

C. What underlying causes might account for significant indicator rates or activity? Please rate each factor in terms of the relative importance for interpreting indicator data.

1. Patient based factors

a) Severity of illness

	Not Important				Very Important
1. history of rapid labor	1	2	3	4	5
2. congenital anomalies	1	2	3	4	5
3. _____	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

b) Co-morbid conditions

	Not Important				Very Important
1. immunocompromised host	1	2	3	4	5
2. _____	1	2	3	4	5
3. _____	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

c) Other factors outside the institution's control contributing to adverse patient outcomes.

	Not Important				Very Important
1. Pt's residence i.e., limited access to facilities	1	2	3	4	5
2. patient choice	1	2	3	4	5
3. patient compliance	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

AFT

2. Practitioner-based factors

	Not Important				Very Important
a. poor physician judgement	1	2	3	4	5
b. physician convenience	1	2	3	4	5
c. _____	1	2	3	4	5
d. _____	1	2	3	4	5
e. _____	1	2	3	4	5
f. _____	1	2	3	4	5

3. Organization-based factors

	Not Important				Very Important
a. physician availability	1	2	3	4	5
b. availability of staff	1	2	3	4	5
c. _____	1	2	3	4	5
d. _____	1	2	3	4	5
e. _____	1	2	3	4	5
f. _____	1	2	3	4	5

D. Identify critical objective data elements/documentation and sources that would capture the information necessary to assess these underlying causes.

1. Patient factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

DRAFT

2. Practitioner factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

3. Organizational factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

VI **REFERENCES**

DRAFT

CLINICAL INDICATOR DEVELOPMENT FORM

I INDICATOR

CABG#1: Post-operative mortality of patients receiving isolated primary and subsequent CABG procedures subgrouped by elective and emergency procedures.

II DEFINITION OF TERMS

A) Terms related to data elements or sources of information.

Post-operative mortality: occurring post CABG procedure with discharge disposition of death during same hospitalization.

Isolated CABG procedure: CABG defined by ICD-9-CM codes 36.10 - 36.19 with no simultaneous valve replacement/repair (35.-), ventricular aneurysm resection (37.32-.33), carotid endarterectomy (38.12) or other major peripheral vascular procedures (38.44-.45)

Subsequent: a reoperation one or more months after primary CABG.

Elective: scheduled or non-emergent cases.

Emergency: those cases deemed to require emergent intervention.

B) Indicator Population Analytic Criteria

1) Subcategories:
   1) Elective, primary isolated CABG
   2) Emergency, non-scheduled, primary isolated CABG
   3) Elective, subsequent, isolated CABG
   4) Emergency, subsequent, isolated CABG

2) Numerator(s): Mortality of post-CABG patients as defined above.

3) Denominator(s): Patients with procedures as defined above.

4) Other

DRAFT

III **RATIONALE**

A. Please explain why this indicator would be useful to assess and specify the process or outcome that would be monitored.

Post operative mortality for CABG procedures, although not necessarily a sentinel event, represents a highly significant outcome potentially related to quality of care. Expected mortality rates may be established for CABG by comparison to peer institutions, with patients subgrouped by the above types as a means of comparing patients with somewhat similar risks. Rates which exceed those of peer institutions may indicate poor quality of care.

B. Please list the aspects of quality and/or appropriateness of patient care that would be assessed by this indicator.

1. Technical skill in performing CABG.
2. Adequacy of post-operative monitoring
3. Adequacy of patient management by clinical staff
4. Judgement in patient selection.

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IV DATA SOURCES

Please identify the source of documentation from those listed in Appendix A (e.g., anesthesia report) for each data element listed on the left.

Data Elements	Data Source/Document
1. OR procedure time	a. operative report/record
	b. anesthesia record
	c.
2. Disposition status	a. face sheet
	b. death certificate
	c. physician's progress note
3. ICD-9-CM procedure 36.10 - 36.19	a. operative report
	b. face sheet
	c. discharge summary
4. Note of previous CABG	a. history & physical
	b. physician's progress note
	c.
5. Emergent/elective status	a. OR schedule
	b. cath lab report
	c. OR report
	d. MD progress notes

DRAFT

4

V. INDICATOR EVALUATION

A. Does this indicator identify sentinel events (all occurrences warrant investigation) or is this a relative rate indicator (further assessment occurs if institution shows trend or is a statistical outlier compared to peers)?

Circle One: Sentinel Event Relative Rate

1) If relative rate, are there currently recognized acceptable rates of occurrence? Yes ___ (Acceptable Rate ___ %) No ___

If yes, what is the source for this rate?

	Specific Reference
Research Literature	_____
Professional Guidelines	_____
Textbooks	_____
Other	_____

2) Are there existing databases from which indicator occurrence rates and/or institutional variance may be established/ verified? Yes ____ No ____

If yes, please list the databases and their location.

Databases	Location
a. _____	_____
b. _____	_____
c. _____	_____
d. _____	_____

B. Please rate the importance of each aspect of care listed in III B relative to indicator activity.

	Somewhat Important	Important	Very Important	Essential
Aspect 1 _____	1	2	3	4
Aspect 2 _____	1	2	3	4
Aspect 3 _____	1	2	3	4
Aspect 4 _____	1	2	3	4
Aspect 5 _____	1	2	3	4

DRAFT

5

C. What underlying causes might account for significant indicator rates or activity? Please rate each factor in terms of the relative importance for interpreting indicator data.

1. Patient based factors

a) Severity of illness

	Not Important				Very Important
1. left ventricular dysfunction	1	2	3	4	5
2. recent MI	1	2	3	4	5
3. left main coronary disease	1	2	3	4	5
4. emergent status	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

b) Co-morbid conditions

	Not Important				Very Important
1. second form of organic heart disease	1	2	3	4	5
2. history of major arrhythmia events	1	2	3	4	5
3. diabetes (insulin dependent)	1	2	3	4	5
4. CHF	1	2	3	4	5
5. peripheral vascular disease	1	2	3	4	5
6. _____	1	2	3	4	5

c) Other factors outside the institution's control contributing to adverse patient outcomes.

	Not Important				Very Important
1. age	1	2	3	4	5
2. smoker	1	2	3	4	5
3. gender	1	2	3	4	5
4. body surface area < 0.8 > 2.0	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

DRAFT

6

2. Practitioner-based factors

	Not Important				Very Important
a. quality of anesthesiology	1	2	3	4	5
b. prolonged bypass	1	2	3	4	5
c. too few CABG's per year	1	2	3	4	5
d. certified perfusionist experience adequate	1	2	3	4	5
e. poor arrhythmia control	1	2	3	4	5
f. incomplete revascularization	1	2	3	4	5
g. selection and timing of surgery patient	1	2	3	4	5
h. adequacy of respiratory therapist	1	2	3	4	5

3. Organization-based factors

	Not Important				Very Important
a. poor interdisciplinary communication	1	2	3	4	5
b. staff shortages	1	2	3	4	5
c. inaccurate lab results	1	2	3	4	5
d. monitoring and maintenance of equipment	1	2	3	4	5
e. inadequate supplies	1	2	3	4	5
f. availability of experienced doctors-post surgery	1	2	3	4	5
g. adequacy of credentialling process	1	2	3	4	5

DRAFT

D. Identify critical objective data elements/documentation and sources that would capture the information necessary to assess these underlying causes.

1. Patient factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

DRAFT

2. Practitioner factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

3. Organizational factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

VI REFERENCES

DRAFT

CLINICAL INDICATOR DEVELOPMENT FORM

I INDICATOR

6(ED): Trauma patient with diagnosis of epidural or subdural brain hematoma receiving craniotomy greater than 4 hours after ED arrival (excluding ICP monitoring).

II DEFINITION OF TERMS

A) Terms related to data elements or sources of information.

Diagnosis: principal or secondary discharge diagnosis and/or autopsy findings.

Epidural or subdural brain hematoma: accumulation of blood in the epidural or subdural space secondary to post-traumatic blood vessel wall damage. ICD-9-CM 852.2- through 852.5-.

Craniotomy: incision into the cranium excluding burr holes. ICD-9-CM 01.24 (except/excluding 01.24 for Burr holes only) and 02.02.

Excluding ICP Monitoring: Intracranial pressure monitoring ICD-9-CM 01.18.

B) Indicator Population Analytic Criteria

1) Subcategories: 1. Pediatric
2. Adult

2) Numerator(s): Number of trauma patients with diagnosis of epidural or subdural brain hematoma receiving craniotomy greater than 4 hours after ED arrival.

3) Denominator(s): Number of trauma patients with diagnosis of epidural or subdural brain hematoma receiving craniotomy.

4) Other:

DRAFT

III RATIONALE

A. Please explain why this indicator would be useful to assess and specify the process or outcome that would be monitored.

The treatment of epidural and subdural hematomas involves the process of evacuation of the hemorrhage and control of the bleeding through a large craniotomy. Without treatment, the brainstem may be compressed by hemorrhage, edema and herniation until death results. Delay in receiving craniotomy increases the likelihood of morbidity and mortality and may indicate problems in the quality and/or appropriateness of patient care. High rates of this indicator in comparison to peer institutions would signal the need for further investigation.

B. Please list the aspects of quality and/or appropriateness of patient care that would be assessed by this indicator.

1. Accuracy of diagnosis by physicians in the ED.
2. Appropriateness of clinical decision by physicians in the ED including neurosurgeons.
3. Efficiency of system for obtaining head CT scans.
4. Timeliness of neurosurgeon response to ED.
5. Availability of resources.

DRAFT

IV DATA SOURCES

Please identify the source of documentation from those listed in Appendix A (e.g., anesthesia report) for each data element listed on the left.

Data Elements	Data Source/Document
1. Diagnoses and procedures: ICD-9-CM for craniotomy	a. inpatient MR (face sheet)
ICD-9-CM for epidural or subdural brain hematoma.	b. ED record
ICD-9-CM for ICP monitoring.	c. billing system
2. ED arrival time	a. ED record (triage, registration, MD or nursing notes)
	b.
	c.
3. time of craniotomy	a. pre-op record
	b. inpatient MR (anesthesia record)
	c.
4.	a.
	b.
	c.
5.	a.
	b.
	c.

DRAFT

4

V. INDICATOR EVALUATION

A. Does this indicator identify sentinel events (all occurrences warrant investigation) or is this a relative rate indicator (further assessment occurs if institution shows trend or is a statistical outlier compared to peers)?

Circle One: Sentinel Event Relative Rate

1) If relative rate, are there currently recognized acceptable rates of occurrence? Yes ___ (Acceptable Rate ___ %) No ___

If yes, what is the source for this rate?

	Specific Reference
Research Literature	_____
Professional Guidelines	_____
Textbooks	_____
Other	_____

2) Are there existing databases from which indicator occurrence rates and/or institutional variance may be established/ verified? Yes ____ No ____

If yes, please list the databases and their location.

Databases	Location
a. _____	_____
b. _____	_____
c. _____	_____
d. _____	_____

B. Please rate the importance of each aspect of care listed in III B relative to indicator activity.

		Somewhat Important	Important	Very Important	Essential
Aspect 1	Acc diagnosis	1	2	3	4
Aspect 2	App decision	1	2	3	4
Aspect 3	Effy system	1	2	3	4
Aspect 4	neuro response	1	2	3	4
Aspect 5	avail resources	1	2	3	4

5

C. What underlying causes might account for significant indicator rates or activity? Please rate each factor in terms of the relative importance for interpreting indicator data.

1. Patient based factors

a) Severity of illness

	Not Important				Very Important
1. patients with Glasgow coma scale greater than 12 upon ED arrival	1	2	3	4	5
2. OR priority for life threatening injuries	1	2	3	4	5
3. _____	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

b) Co-morbid conditions

	Not Important				Very Important
1. acute alcohol/drug intoxication	1	2	3	4	5
2. disruptive patient	1	2	3	4	5
3. _____	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

c) Other factors outside the institution's control contributing to adverse patient outcomes.

	Not Important				Very Important
1. multiple trauma patients	1	2	3	4	5
2. refusal of consent	1	2	3	4	5
3. _____	1	2	3	4	5
4. _____	1	2	3	4	5
5. _____	1	2	3	4	5
6. _____	1	2	3	4	5

2. Practitioner-based factors

	Not Important				Very Important
a. inadequate training or inexperience of physicians	1	2	3	4	5
b. fatigue or illness	1	2	3	4	5
c. inadequate monitoring of patient by ED staff	1	2	3	4	5
d. unavailability of anesthesiologist	1	2	3	4	5
e. timeliness of neurosurgeon response	1	2	3	4	5
f. _____	1	2	3	4	5

3. Organization-based factors

	Not Important				Very Important
a. inadequate staffing of ED with physicians	1	2	3	4	5
b. inadequate on-going review of physician performance	1	2	3	4	5
c. inefficiency of ED systems to obtain CT scan	1	2	3	4	5
d. unavailability of radiologists	1	2	3	4	5
e. unavailability of CT scan technician	1	2	3	4	5
f. unavailability of staff to transport patient	1	2	3	4	5
g. unavailability of CT scanner	1	2	3	4	5
h. unavailability of OR	1	2	3	4	5
i. unavailability of anesthesia	1	2	3	4	5
j. inadequate correction of identified QA problems	1	2	3	4	5
k. unavailability of OR resources	1	2	3	4	5

DRAFT

D. Identify critical objective data elements/documentation and sources that would capture the information necessary to assess these underlying causes.

1. Patient factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

DRAFT

2. Practitioner factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

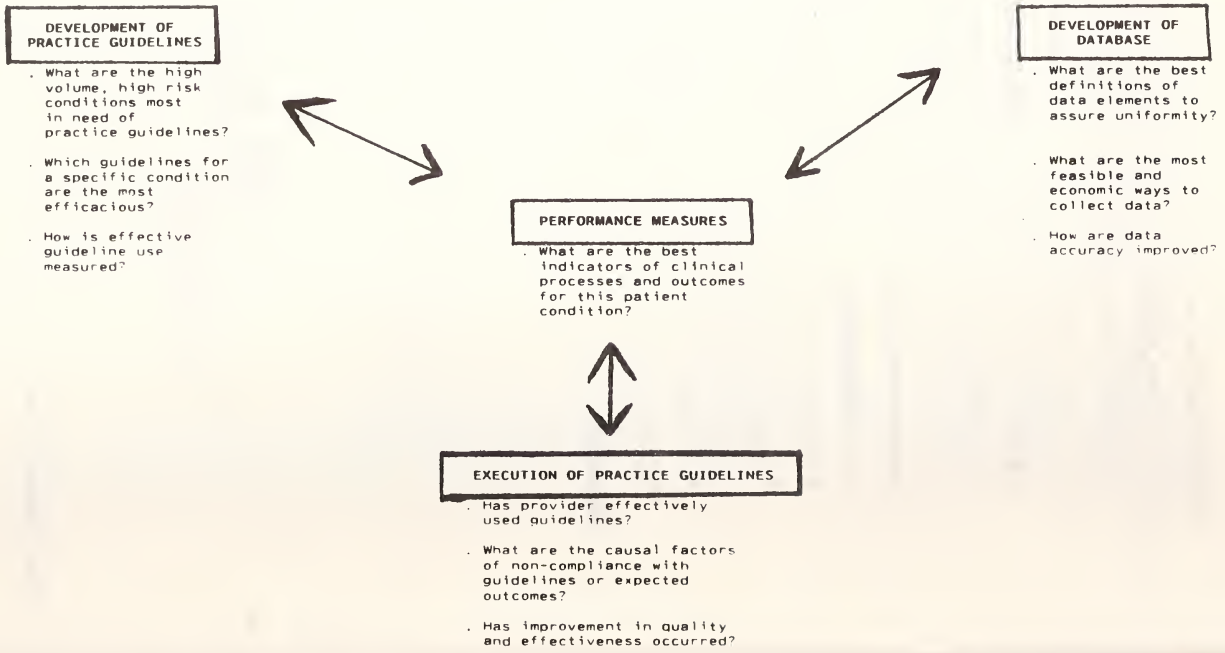
3. Organizational factors

	Data Element	Source
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____

VI REFERENCES

DRAFT

EXHIBIT III


DEVELOPMENT OF PRACTICE GUIDELINES
. What are the high volume, high risk conditions most in need of practice guidelines?
. Which guidelines for a specific condition are the most efficacious?
. How is effective guideline use measured?
DEVELOPMENT OF DATABASE
. What are the best definitions of data elements to assure uniformity?
. What are the most feasible and economic ways to collect data?
. How are data accuracy improved?
PERFORMANCE MEASURES
. What are the best indicators of clinical processes and outcomes for this patient condition?
EXECUTION OF PRACTICE GUIDELINES
. Has provider effectively used guidelines?
. What are the causal factors of non-compliance with guidelines or expected outcomes?
. Has improvement in quality and effectiveness occurred?

Chairman STARK. Thank you very much.
Dr. Cooper.

STATEMENT OF RICHARD A. COOPER, M.D., DEAN AND EXECUTIVE VICE PRESIDENT, MEDICAL COLLEGE OF WISCONSIN

Dr. COOPER. Chairman Stark, Mr. Gradison, and members of the committee, I am Buz Cooper, dean of the Medical College of Wisconsin. I would like to thank you for inviting me to be here today. I would like to particularly thank Jim Moody for making this appearance possible.

I strongly support effectiveness research, and I strongly support H.R. 1692, which I believe will make a very positive impact on this field.

Let me make three points about this approach. First, effectiveness research has the ability to deal both with cost and with patient care outcomes. Second, its ultimate goal must be to provide health care workers with the skills and tools they need to improve the way they practice medicine. Third, many of the resulting outcome measurements and practice guidelines will raise important bioethical considerations.

While many factors impact on health care costs, one important factor is the choices that physicians make for their patients. I believe physicians are concerned about issues of quality and issues of cost, and they are anxious to participate in a process that assesses clinical outcomes. As physicians, we are taught to critically evaluate the care of each patient we treat in the context of a broad base of information and body of attitudes. However, we rarely analyze all of our patients who have the same disease or who receive the same therapy.

How effective is our care? Recalling cases from memory just is not good enough. As educators, we must prepare tomorrow's physicians for this essential role, and today's practicing physicians must be given the tools and skills they need to analyze and improve their own patterns of practice.

The Medical College of Wisconsin has undertaken an ambitious project to deal with issues of cost, quality, and bioethics. We call it our Health Information Technology Center. It draws our educational and research strengths to unite urban and rural hospitals in a regional network linked to national systems.

The approach we have taken is consistent with what I would refer to as the prescription for health effectiveness advocated by Roper and his coworkers. Our effort already has a strong relation to HCFA. For example, my colleagues have worked closely with HCFA analyzing and validating Medicare claims data as a research resource. To facilitate better measures of hospital quality, they have merged the Medicare resource with both the American Hospital Association data base and with the National Peer Review Organization data.

Vast quantities of data must be rapidly handled in these kinds of analyses. My colleagues have constructed new computers, and they are designing software specifically for this purpose. It will permit peer review organizations to obtain outcomes and track effective-

ness longitudinally over time. We are quite excited about the potential of this kind of project.

These and other avenues of research will certainly provide guidelines for practice, and they will provide benchmarks against which local experiences can be analyzed and compared. Both are important national and local perspectives.

But the research will also raise ethical issues. For example, how do we translate outcome measurements into clinical decisions concerning the proper use of scarce organs for transplantation? These decisions are both statistical and ethical. Recognizing the importance of medical ethics, we established a Center for the Study of Bioethics 7 years ago. Because ethical issues are shared concerns, we have also established one of the Nation's three original bioethics networks: The Wisconsin Ethics Committee. It is the largest and most sophisticated network, I believe, that is in operation today, boasting a membership of more than 80.

Our Health Information Technology Center will overlay the bioethics network with a regional network for health policy and effectiveness research, and with our library informatics network. In so doing, it will create a regional common ground for dealing with some of the fundamental issues which confront those making clinical decisions.

Let me conclude by saying that we believe effectiveness measures are an essential part of the practice of medicine. As you deliberate on future funding for this field, I urge you to consider the several goals we have defined for ourselves.

First, as educators, we must enhance the skills of today's practitioners while educating the caregivers of tomorrow.

Second, as leaders of the academic health centers, we must establish regional networks to find shared solutions to the shared problems of cost, quality, and bioethics.

Third, as scientists interested in health policy, we must extend the capability and power of data resources available nationally, and we must bridge them to care providers regionally and locally.

Tomorrow's world will surely include expanding medical knowledge and technical capability. Managing this explosion of information and technology is one of the great challenges we face as we strive for a quality health care system that we as a nation can afford.

In closing, I want to compliment you for bringing forth this important legislation, and I want to thank you for allowing me to share these thoughts with you today.

[The statement of Dr. Cooper follows:]

Testimony of Richard A. Cooper, M.D.
Dean and Executive Vice President of the
Medical College of Wisconsin
Before the
Health Subcommittee
House Ways and Means Committee
May 24, 1989

Mr. Chairman and Members of the Sub-Committee:

Thank you for the opportunity to appear before you today. I particularly would like to thank my own congressman -- Jim Moody -- for making my appearance possible.

I should like to begin by expressing the view that the best way to control health care costs while simultaneously improving the quality of care provided is through effectiveness research. What is effectiveness research? It is the process of examining the costs and outcomes of what we do for patients -- the process of assessing new technologies and the ever-increasing number of diagnostic and therapeutic possibilities. It has as its goal modifying the practice of medicine. I believe effectiveness research is in the best interests of our patients.

Before discussing the work we are doing at the Medical College of Wisconsin, I would like to share a number of observations that may be useful to you as you deliberate on future funding for this field.

First, we no longer live in an environment where medical decisions can be made without thought to cost considerations. Medical and financial resources are scarce and valuable commodities. Effectiveness research must deal with both cost considerations and patient outcomes.

Second, the ultimate purpose of an effectiveness program is to provide health care workers with the skills and tools that they need to improve the way they practice medicine.

Third, the application of effectiveness research to the delivery of patient care will bring bioethical considerations into play. Health care providers must be prepared to address these ethical considerations.

The approach to effectiveness research that we have taken at the Medical College of Wisconsin is based on the belief that physicians wish to practice high quality, cost-effective medicine. The competitive model of medical care that we now seem to have in the US has, I believe, increased costs and adversely modified physician behavior. This has been further accentuated by the defensive posture of medical practice in a climate of audit and litigation. These will have to be dealt with separately. However, I should like to express the view that effectiveness research promises to provide practitioners of medicine with the tools to develop their own means of reaching for quality, based on continuous monitoring of outcomes and continuous improvement in the delivery system.

The elastic nature of the health care system continues to shift costs, as one or another payor source develops a temporarily-effective strategy for cutting its share. Inelastic pockets have developed recently due to the uncoordinated but added effects of several payors -- as we now are seeing in the financial plight of hospitals in New York and Massachusetts. Nonetheless, health care costs as a fraction of the Gross National Product continue to rise. Each day there is more that is possible to accomplish clinically for more people, and all of us want what's best for ourselves and our families. And there are expanding numbers of medically needy individuals, including

the elderly, those with AIDS, those ravished by drugs and alcohol and those suffering the medical consequences of poverty.

While it is apparent that there are many factors within our health care system which impact on cost, I believe that an additional and important factor is physician behavior; that is, the choices physicians make for their patients. Moreover, I believe physicians are concerned about issues of quality and cost. They are anxious to participate in a process that assesses clinical outcomes. However, while epidemiologists have long advocated and practiced this approach to analyzing our health care system, the tools of epidemiology are not widespread among practitioners of medicine.

As physicians, we are taught to critically analyze the care of each patient we treat in the context of a broad body of information and attitudes, including the medical literature, our perception of what is right based on recollections from our own experience and that of our colleagues, and our understanding of the value of various technologies and procedures. In general, we do not analyze our collective experience -- for example, all the patients with a given disease that we have treated or that have been treated in our hospital. A friend of mine, a hematologist, related his frustration in attempting to collect the experiences his group had in treating TTP, an uncommon bleeding disorder. They saw 5 or 6 patients a year, but over several years had a significant experience. How were their patients doing? Recalling cases from memory is just not sufficient.

To be sure, there are many examples of successful analyses, but they are the exception rather than the rule. We as educators have not adequately prepared physicians for this essential part of their job. We are beginning to do so in our medical schools today. We are also trying to meet the need for physicians specifically trained in mathematics and computer science who will be critical for bridging data analysis and patient care. And we recognize that we have the obligation to provide today's practicing physicians with the tools and skills necessary for them to analyze and improve their own patterns of practice.

To meet these needs, we at the Medical College of Wisconsin have begun what some have called "a bold step" toward health care of the future. We call it the Health Information Technology Center. It is built on the principle of networking. It places our educational resources and research strengths in the center of the network.

I envision the process of effectiveness research as a linear continuum similar to two highways on opposite sides of a river. On one side is the highway of the raw patient data accumulated by state agencies and third-party payors. On the other side is the highway of health care providers; physicians, nurses and administrators responsible for clinical decisions. The only way to connect the two paths is to build a bridge. The bridge is the structure for analysis, interpretation and communication. I view our Health Information Technology Center as an example of the kind of connecting bridge that this nation will have to build if we are to impact on the cost and quality of the health care we provided.

We recognize the enormous power of data sets such as Medicare claims or the State of Wisconsin uniform hospital discharge summary data. Like gold mines waiting to be mined, they hold important clues to effective patient care. These data sets provide a view of the world of health care much like a satellite photo sees a city, often revealing surprising detail, sometimes misinterpreting images, while obscuring other details altogether. Yet, they represent a useful beginning. The true picture emerges when further examined by those on the ground -- physicians and hospital administrators who analyze their local

clinical experience in the context of regional and national norms -- when the two paths are bridged.

The approach we have taken is consistent with Roper's prescription for health effectiveness. It involves the creation and analysis of large data sets, the assessment of variation through focused research and the feedback and education of the care provider. Moreover, by making Medicare claims files available for effectiveness research, Dr. Roper and his co-workers at HCFA have created a valuable national research resource. My colleagues at the Medical College of Wisconsin have worked in close partnership with HCFA in analyzing and validating this data resource. They have had a long history of working with large data sets, having created the international bone marrow transplant registry, an important international resource which they have managed for many years.

One of the most intriguing exercises they are doing is merging several of the existing national databases. For example, they have successfully merged the American Hospital Association database with Medicare claims data, and this has been merged with National Peer Review Organization (PRO) data for purposes of evaluating the quality of care in US hospitals.

They have taken several different tacks in their work with HCFA to develop models that will allow the use of Medicare claims data to estimate health care quality. The first was to review HCFA's use of hospital mortality rates to assess quality of care and to validate this methodology. The second was an analysis of the hospital characteristics that may have an impact on quality of care. Using Medicare data for example, my colleagues have shown for the first time on a national basis that physician board certification is associated with an improved quality of care, as measured by hospital mortality.

The vast quantities of data that must be handled in these kinds of analyses require rapid computer processing. Faculty in our Health Information Technology Center have constructed new computers and are designing software specifically for this purpose. These computers will be able to handle large quantities of data at high speeds. The software will permit the Peer Review Organizations (PRO) to perform longitudinal outcome analyses, thus allowing them to obtain outcomes and track effectiveness over time. In addition, the PROs will be able to communicate with each other, to compare data and determine for example, if geographic variations exist. We are very excited about the potential of this project.

These and other avenues of effectiveness research will surely provide guidelines for the practice of medicine and bench marks against which local experiences can be compared and, if indicated, modified. But this research will also focus questions which are difficult to deal with. For example, how do we translate outcome measurements into clinical decisions concerning who should or should not receive an organ transplant. The issues are both statistical and ethical.

The Medical College of Wisconsin has recognized that clinical decision making cannot exist in an ethical vacuum. Seven years ago, we created the Center for the Study of Bioethics. This Center was established to foster the study of bioethics in the delivery of health care.

Ethical issues are shared issues. As part of our effort to serve the State of Wisconsin, we have established one of the nation's three original bioethics networks: the Wisconsin Ethics Committee. It is one of the largest and most sophisticated networks currently in operation. It boasts a membership of more than 80, and continues to grow.

The overwhelming success of our Bioethics Center and the Wisconsin Ethics Committee Network is due to its practical approach to ethical issues which face care givers every day. Currently, the Medical College of Wisconsin is participating on an advisory board developed through the Hastings Bioethics Center in an attempt to link the dozen or so existing bioethics networks nationally.

Our Health Information Technology Center will overlay our Bioethics Network, our Network for Quality Assurance and Effectiveness Research and a Network for Library Informatics. In so doing, it will create a regional "common ground" for dealing with some of the fundamental issues which confront those making clinical decisions.

We have found that, while networking is important for all hospitals, it is particularly important for rural hospitals. As an academic health center, we recognized that we have a special responsibility for facilitating this kind of communication among hospitals in our region, and linking our regional network to national systems. In an article in the Annals of Internal Medicine last December, Niemera forcefully pointed out that, until such networking is accomplished, rural hospitals will "grapple in isolation, rediscovering what other hospitals have already learned, using limited resources that could have been better spent, and settling for less than what is possible simply because it is too hard to do it alone."

CONCLUSION

We at the Medical College of Wisconsin believe that effectiveness research -- that is, the process of examining the cost and quality outcomes of what we do -- the process of assessing the ever-increasing number of technologies which are designed to enhance our ability to provide care -- effectiveness research is an essential part of the practice of medicine. As educators, we must enhance the skills of today's practitioners, while educating the care givers of tomorrow. As academic health centers, we must establish regional networks to find shared solutions to the shared problems of cost, quality and bioethics. As scientists interested in health policy, we must extend the capability and power of data resources available nationally, and we must bridge them to care providers regionally and locally.

Tomorrow's world will be more complex than today's, with the ability to do more and more for patients. Managing this explosion of information and technology is one of the great challenges we face, as we strive for a quality health care system that we as a nation can afford.

Thank you for allowing me to share my thoughts with you today.

Chairman STARK. Mr. Moody.

Mr. MOODY. Thank you, Mr. Chairman. I appreciate the chance to question first since I have to introduce the head of the U.N. Population Agency at a luncheon in a few minutes.

Dr. Cooper, thank you for being here. I do not know if you heard my exchange with Dr. Sullivan earlier in the morning that economics has to be brought together. A scientific solution itself will not lead us to where we want to go, given the environment of cost constraint that will be with us for the indefinite future.

Did you have any additional comments on it? Do you agree with my point, or was I off base?

Dr. COOPER. Well, I really do basically agree with your point, and I think the comments I have made also agree with that point. I think outcomes—there are many outcomes. As was pointed out previously this morning, there are quality outcomes and there are cost outcomes. And we want to know the outcomes generally. Then we can begin to balance things, and we will be facing difficult decisions. And I tried to emphasize in a few comments a moment ago that some of these decisions are practical and some of these, in fact, are ethical.

So it is often easier to work in a vacuum of no knowledge. One can make decisions almost easier under those circumstances, but what we want is real knowledge. Faced with real knowledge, then we are faced with real choices of cost and quality and including ethical issues.

Mr. MOODY. So there is a simultaneity here of economic considerations, along with scientifically appropriate considerations.

Dr. COOPER. I think it is all one big ball of wax.

Mr. MOODY. And I compliment you on bringing the third element in, which was the ethical. There is no way, in the end, we are going to get around ethical considerations. Once resources are scarce, we are going to be facing very tough ethical issues. And I think coming to grips with those is excellent, and I know we are going to learn a lot from that.

One thing that occurs to me from reading your excellent prospectus, as well as your testimony, is how in the world are we able to manage the literal explosion of information and data? I mean, it is almost an overwhelming embarrassment of riches. And how you manage that and make sense out of it and reach these cost-effective, bioethical, relevant decisions seems to me a real tough issue.

Dr. COOPER. I agree. I think it is probably one of the issues that physicians are so concerned about. You heard a moment ago reference to the fact that many of the analyses are retrospective analyses. They are of interest, but they are hardly necessarily guidelines for what we can do today and tomorrow. The medical literature expands so rapidly. Physicians are coping with the latest literature, while guidelines are being developed for historic practice.

Mr. MOODY. Like generals fighting the last war, almost.

Dr. COOPER. Often.

So I think what you are alluding to is a very important aspect of this. If we are to have physicians operating in the most effective framework, then they have to have ready access to information: The information from effectiveness programs, the information from the medical literature. The National Library of Medicine has been

a very important resource. Regional informatics networks are very important sources. We play that role for many hospitals and physicians in Wisconsin.

But I think they are interlinked. Informatics, measurements of quality, measurements of cost all have in common examining what we do on a daily basis. It is an ethic. It is an approach to the world. It is a mindset of a physician. The mindset is to both do and then to reflect on what we have done, both play the game on Sunday afternoon but also be our own Monday morning quarterback. It is an approach that many of the speakers today, all the speakers today, share, but it is an approach that is not shared, it has not been transmitted to generations of physicians.

I believe that a principal responsibility we as educators have is to modify the mindset of physicians so that they take as a personal responsibility and as simply a part of the course of what they do on a daily basis, doing and examining what they are doing. And we can help them do that if we give them the tools, and some of those tools are easy access to medical information through modern informatics systems.

Mr. MOODY. Thank you very much.

Chairman STARK. Dr. O'Leary, you deal primarily with hospitals, your organization?

Dr. O'LEARY. That is our largest accreditation program. We do have six other accreditation programs.

Chairman STARK. Because of my concern or sensitivity about the Federal Government overriding consideration of cost savings—and I might interpret that to think that we might put dollars ahead of quality. Do you want to comment on what you think the overall effect of the DRG system has had on the quality of hospitals?

I guess we could be accused—I wasn't here when we built the DRG system—of saying that we disregarded quality in that program. Do you have any comment? I mean, are the hospitals of as high quality today as they were in 1983, on the average?

Dr. O'LEARY. My impression is, on the average, that hospitals are fundamentally at the same level of quality that they were say 10 years or more ago. But I would introduce a caveat that the world of health care and hospitals a decade ago was not as idyllic as it was believed to be at that time, nor is it quite as awful as it is sometimes portrayed today.

But today, the technological advances have brought a lot of additional pressures to bear. Our population is older. Our patients have more diseases and they are more vulnerable. So the ante for paying attention to what we are doing inside hospitals has gone up. I think that is the reality of our environment.

But the DRG's, I think, had a desired effect of making people look at the prudent management of resources. I do not see any definitive indicators yet that the quality has been adversely affected. I do worry, as I am sure you do, that we can reach a point where resource constraint is so great, as laid against demand, that we will start to see some quality impacts.

We have recently provided some data in testimony in the State of New York, which is a State where resource constraints for hospitals have been tighter for a longer period of time, where you now are starting to see some real quality of care effects. But I think

that is an isolated instance right now and not attributable to the DRG system.

Chairman STARK. Thank you. Dr. Cooper—let me hold on to this for a minute. Let me go to Dr. Wilbur. I gather that you are concerned about the normative concerns, not necessarily what we can do but maybe what we ought to do prospectively. I thought I read into your testimony that if outcomes research—and thereby perhaps some guidelines that would evolve within practice, not necessarily imposed on practice—would somehow have a stultifying effect on physicians' willingness to try new procedures, and indeed to take advantage of new developments as they come along, and we might slow down development of new cures, new drugs, new procedures. Is that a concern that I read into your testimony or did I miss that?

Dr. WILBUR. Mr. Chairman, you are absolutely right. It is a serious concern that no matter how beautifully a set of guidelines are developed today, no matter how much talent is put into them, they will no longer be appropriate in the future. For instance, supposing you were today to set guidelines for the proper treatment of AIDS. You probably could not get them published before we had to have a new set of guidelines.

What we are suggesting is not that we should not set guidelines. We are agreeing on that very much, but they should allow for flexibility and innovation. We are saying that the keeper of the guidelines has to be an active, ongoing organization. That to set up a consortium somewhere and have them come up with guidelines, no matter how perfect, is not a long-term answer.

Chairman STARK. But I guess I wanted to go just a little further. Do you feel that just focusing attention on outcomes, you know, Monday morning quarterbacking as I think Dr. Cooper suggested, is going to put the profession, not any individual practitioner, so concerned? I mean, it is like reading scores for teachers. If the class is not graduating with a higher reading score than the class in the high school next door, you somehow worry and you begin to teach to the reading score, not teach to get kids to enjoy reading. Are we apt in this, or is there something we can write into it, to dampen enthusiasm for experimenting and innovating?

Dr. WILBUR. I think only those who are at the lower echelons of practice are really threatened, others have been helped. The guidelines set by the American College of Obstetricians and Gynecologists have been used during professional liability trials. As long as that fellow of the college had adhered to the standards, he or she was defended by them. So the standards were not a threat, they were an actual assistance.

The standards set by the anesthesiologists for monitoring have been utilized in hospitals, have reduced the number of deaths, and also, incidentally, the malpractice premiums paid by the anesthesiologists. They think they are doing a wonderful thing. They are not threatened at all by them. They find themselves enormously helped by them.

So that most of the people who have looked at the guidelines are happy with the idea, unless as was brought out earlier, we go to cookbook medicine. If we ever get to where the guidelines say, for instance, that there are eight steps to take care of a certain proce-

dure, then every physician who arrives at that place in the diagnosis will turn his or her brain off and follow eight steps. Unfortunately, the patient may have only needed three, in which you as the purchaser are paying for five you did not need to, or possibly this was the patient who needed an extra several steps. The physician going down the cookbook list has not really paid attention to the individual. That way, they would be disastrous.

Chairman STARK. I am thinking of an anecdote about cookbook medicine, but I think I will skip it for now. No, I will not.

I would just suggest as a lay person, anyone who thinks that, or any physician who worries that members of the public will, with a cookbook, take over their practice, that they ask a lay person to buy one of those pregnancy tests on the drugstore shelf and then find that they do not end up buying three because they are not really sure they can tell what color it is anyway, and without somehow—whatever it is in the practice of medicine that gives you the assurance of your decision, I think this is always a good way to at least assuage the fears of doctors that a cookbook available will make instant physicians out of all of us. That is what little I can do to assure you that that will not happen.

In your testimony, Dr. Cooper, you talk about some data that you gathered that indicated that physician board certification has some direct correlation with quality of care. Is that a fair assessment of the statement you made of some research you did at Wisconsin?

Dr. COOPER. Not Marquette anymore. Were now called the Medical College of Wisconsin. Work by Dr. Rimm and his colleagues at the Medical College of Wisconsin utilizing the HCFA database looked at mortality as a measure of quality in hospitals and looked at a variety of parameters that might correlate with varying hospital mortality, hospital characteristics.

Chairman STARK. In your statement, is physician board certification, for a specialist being certified by that board?

Dr. COOPER. Yes.

Chairman STARK. Or a hospital board?

Dr. COOPER. No, specialty board certification. There was a correlation in that study of the hospitals that had a lower than expected mortality had a reasonable correlation with a high fraction of specialty board certified physicians. And the contrary was true for hospitals with few subspecialty boarded physicians.

These kinds of overview studies are possible in these large data sets. They tell us something about the practice of medicine. But I think other kinds of studies in the trenches are equally important.

Chairman STARK. In responsing to Dr. Wilbur's statement just a moment ago, you used a phrase that I would like to pick up on. You talked about the lower echelons of practice. I guess as we get into—and since I have served on this committee, I have always been troubled with the automatic—I would stipulate to being a knee-jerk liberal, but I also find this knee-jerk association with price and quality. I mean, I am not buying groceries at the A&P, I am trying to provide care to Medicare beneficiaries.

I have always felt that while there may be echelons of expertise in your profession, that as long as we insist on a minimum standard of quality, whether that is board certification or just State licensure—I would look at that as two echelons—that we are doing

our job. That we have to depend on academicians, State licensing bureaucracies, and organizations of peers to define a level of quality below which no American should have to be treated. Beyond that, if we are assured that that is there by rule, then we ought to be free to go and bargain for services as best we can.

Do any of you have any problem with that feeling either on an ethical basis or on how it might affect the quality of treatment in this country?

Dr. COOPER. Chairman Stark, I do not know that I have a problem with it, but I think we should aspire for something greater than that. I think the audit system that we have in medicine today, the inspection system as others have referred to in the auto industry, the inspection system that lets that car get off the assembly line because it passed the inspection, it met the minimum criteria, and after 1,000 miles driving it the engine gave out. It is a very common experience for all Americans.

I do not think that is what we want in American medicine. I do not think that is what physicians want for themselves. Quite the opposite. I think the threshold is something that may be important for accreditation, but the quality level that patients should desire and that physicians should aspire for in their practice of medicine is far above the threshold. I think what this legislation does is provide funding which will create tools for physicians to monitor and continually improve and elevate the level of their personal practice.

To be sure, one can define specific diseases. The ones that are easily defined are easiest studied. Cataracts, you can identify cataract surgery. It is a discrete event in a human being's life; or a hysterectomy. But most care is not quite so discrete. Most care is longitudinal care involving multiple steps, not one pristine, easily studied step.

Physicians then cannot rely simply on studies that will define guidelines for these discrete, definable clinical events. There is the mass of medical care that is not well defined in these discrete fashions in which physicians have to have a pattern of behavior where they examine the overall outcomes of how they treat patients and find ways to improve their care by identifying the fact that they are not doing as well as one of their peers.

It would be a big surprise to many physicians that their patients with chronic obstructive pulmonary disease may not be doing as well as another guy across town. In fact, they have no way of knowing. If they knew, they might get together with the guy across town and say, gee, what are we doing different? Why is it that my overall outcomes are not as good as yours? They lose track of their mass of patients being focused on one patient at a time.

That process, which I think is an educational process that begins walking in the door of medical school, that process of examining what you are doing given the tools that we now have by means of computers and data analysis and so forth. I think that process then allows us to aim for an increasing level of care that is, someone used the phrase earlier, self-policed or self-monitored. I think that is what this legislation will accomplish.

Dr. WILBUR. Mr. Chairman, if I might supplement these excellent thoughts. It is true that we do have the certificates, but it is

unfortunately true that they are not necessarily exactly correlated with excellence. There are people without the certificates who really practice quite well, and unfortunately some people who take tests very well who do not take excellent care of their patients for whatever reasons; sometimes they are impaired physicians.

Having guidelines against which to measure the practice, I think is an essential over and above and beyond the certificates you have pointed out, which however should be retained because they are valuable.

Chairman STARK. Do you see, Dr. Wilbur, any direct correlation between basically physician income and physician quality?

Dr. WILBUR. No, sir.

Chairman STARK. Let me just read, and I will paraphrase, because I think this illustration cuts both ways. On the one hand, it may illustrate our not paying hospitals and physicians promptly or enough. and on the other hand, how do you decide what to pay. And see whether this legislation might help us at some point, or these guidelines might help us.

This is a letter which says, "My attention is drawn to point five on the enclosed directive from the 'blank' medical center." It is in my district. "I believe the instructions advise physicians to provide care and guide therapy to promote reimbursement to the hospital rather than what the patient needs. It is my understanding the physician who signed the recommendations"—I will skip that.

"I am astonished and incensed that the chairman of a hospital department would promote activity that I believe borders on fraudulent. On two occasions I have been pressured by reviewing physicians to change diagnosis or diagnostic priorities in order to enhance hospital reimbursement. It is difficult to resist such organized pressure. I wish to preserve my anonymity to avoid the otherwise inescapable retribution." A medical staff member of that medical center.

The point 5—and I do not understand it, so I will read it. This was a memo to the members of the department of family practice. Point 5 says:

> When admitting elderly patients with possible stress fractures, particularly of the lumbar spine, it may be difficult for the hospital to obtain reimbursement for such services, particularly when the admission is of only a short duration and the patient is thereafter placed in a nursing home.
>
> In order to obtain compensation from Medicare, it is recommended that the following treatment considerations be entertained: (*a*) NPO; (*b*) for IV therapy; (*c*) IM medication for pain, X1 minimum; (*d*) NG tube placement, PRN ileus, nausea, vomiting, distention, et cetera. This would then clearly demonstrate that the patient is admitted for control of a serious medical problem with potential for ileus and other complicating factors of acute pain associated with potential compression fractures of the lumbar spine. Playing the game in this manner seems the order of our times.

Signed by the doctor.

Now I do not know what those things are, and maybe they make sense to you gentlemen, but is this the kind of concern—maybe this doctor has a real concern that we are not paying their hospital enough for the quality service that they provide. But maybe also this is a way to just get more money for doing what they ought to do anyway. Is this something that as outcomes research develops into standards of practice that will make it easier for lay people or administrators in this area to determine what we ought to be

paying and whether that is the proper procedure or not, or will that not help at all?

Dr. O'LEARY. No. I think that is a critical, positive feature of this legislation. It is the balancing of the equation, of forces. While a lot of attention has been devoted to reimbursement issues for obvious and very legitimate reasons, we have not devoted our attention to developing an information base about the appropriateness and quality of care.

Information is a very powerful force, and it helps tell us whether we are spending our money correctly, it helps to set reimbursement policy, and it also helps promote self-examination and the building of higher and higher standards of performance as Dr. Cooper has indicated. That is why this is important.

I think that we can look to an incremental building of an information base. We are not looking at the year 2000 with this effort. We will get better and better next year and the year after and so on. But to me, the articulation of this legislation by you and Congressman Gradison is a very tangible statement that we need information in order to make rational decisions.

Chairman STARK. It is not really my legislation. He just puts my name on it in case it goes sour and then he calls it my bill. Anyone else? I mean, is this off base or is this the kind of thing—as I say, things like this are tossed over my transom every night, and I have trouble assessing whether they mean anything or not. But I think that maybe this will get us a little closer. Dr. Wilbur.

Dr. WILBUR. If you had appropriate guidelines for the therapy of fracture of the lumbar vertebrae it certainly would not include starving the patient which those orders did, and one would be able to measure really very clearly that this was inappropriate. I do not know that anywhere in the world you start setting up rules that somebody does not start playing games. If you have guidelines, there is going to be somebody who will spend all night trying to figure out ways to beat the game instead of spending 5 minutes doing it the right way.

Chairman STARK. Do you want to have the last word, Dr. Cooper?

Dr. COOPER. All right. I would like to add just add one word, and that is networking. I think one of the issues that we are dealing with here is communication among physicians in practice, between physicians in practice and health planners looking at large data sets, and in the example you have just given between between physicians in practice and the reimbursement system.

If we are going to make health care in this country effective in terms of quality and effective in terms of cost, then we have to bridge all these different interested parties. Although it is not specifically cited in the legislation, I think it is implicit that communication is key and that regional networking of the sort that you have heard a bit about this morning will play an important role in achieving the goals of the legislation.

Chairman STARK. I want to thank the panel very much, and in absentia thank Congressman Gradison who indeed has enterprised this along with Senator Mitchell and I. It is my hope that we will see this legislation enacted with all the other noncontroversial things we will have in our reconciliation bill next month.

I want to thank the panel very much for their participation. The committee is in recess.

[Whereupon, at 12:40 p.m., the subcommittee hearing was adjourned.]

[Submissions for the record follow:]

STATEMENT OF THE

AMERICAN COLLEGE OF RHEUMATOLOGY

TO THE

HOUSE WAYS AND MEANS SUBCOMMITTEE ON HEALTH

ON THE

MEDICAL CARE QUALITY RESEARCH AND IMPROVEMENT ACT OF 1989
(H.R. 1692)

The American College of Rheumatology (ACR) appreciates this opportunity to comment for the record on H.R. 1692, the "Medical Care Quality Research and Improvement Act of 1989," and specifically, to share its views on practice guidelines.

The American College of Rheumatology is the only professional organization of physicians and scientists devoted to the study and treatment of rheumatic diseases and the education of professionals who care for these disorders. The vast majority of its 4500 members are rheumatologists.

A rheumatologist is a specialist who provides medical care to patients with arthritis, diseases of the immune system and other disorders that cause pain and inflammation of the joints, muscles, and bones. Osteoarthritis, rheumatoid arthritis, gout, systemic lupus erythematosus, bursitis, back pain, and osteoporosis represent some of the more than 100 types of rheumatic diseases, which affect more than 37 million people in the United States and which are the leading cause of disability and absence from work in this country. By special training and expertise, rheumatologists are uniquely qualified among physician specialists to care for people with rheumatic diseases in a high quality and cost-effective manner, and to lead the team of health professionals who assist in treating these diseases.

The ACR commends the Congress, particularly Congressmen Gradison and Stark, sponsors of H.R. 1692, for addressing the issue of quality of medical care. As both health care costs and medical malpractice claims increase, the medical community must meet the challenge implicit in this legislation: that of determining what is and is not effective in medical care, and developing a means of standardizing and utilizing this information. The "Medical Care Quality Research and Improvement Act" is a timely measure.

Of particular interest to the ACR is reference in H.R. 1692 to development of guidelines. The ACR believes that appropriate development of practice guidelines is a means of improving quality of care while controlling the volume of services. Because of our strong support for the development of such guidelines, this statement will focus on this issue.

Practice Guidelines

If developed and applied in an appropriate manner, practice guidelines will be of extreme value to the medical profession in determining appropriate care and controlling volume. There is great need for consensus within the medical community as to what constitutes appropriate care. The rise in medical care costs highlights the need for such a consensus. Medicare costs alone have risen at an average annual rate of 15.5 percent between 1975 and 1987, with 40 percent of this increase (under Part B) resulting from an increase in volume of services. Though it is not clear what portion of this increase is the result of newer technology and treatment options or better access to care, it is clear that there is a need for certain standards as to what constitutes effective care.

It has also become apparent, through the research of John Wennberg, M.D. and others, that there are great variations in the way physicians treat their patients. Some variations can be attributed to differences in medical technology and facilities across communities, but in the majority of cases the differences are purely due to the different approaches taken by physicians.

The potential delivery of inappropriate care is perhaps the strongest justification for development of practice guidelines. An example may be the estimated 17 percent of all coronary angiograms that are performed without appropriate indications, according to the research of Robert Brook, M.D. and Mark Chassin, M.D.

The ACR, in offering strong support of practice guidelines, would suggest several methods of development and application. First, and most importantly, practicing physicians must be involved in guideline development. In developing guidelines for the treatment of rheumatic diseases, rheumatologists should have the lead in determining the range of appropriate procedures to be used in treating, for example, rheumatoid arthritis, osteoarthritis, and systemic lupus erythematosus. Input must come from practicing rheumatologists as well as from those in an academic setting. The views of general practitioners and orthopedists who provide care to patients with rheumatic diseases symptoms must be considered as well. The limited and often non-specific diagnostic techniques available in evaluating patients with rheumatic diseases, and the difficulty in evaluating the results of therapy, make it essential that the rheumatologist play the dominant role in developing any guidelines for management of these diseases.

Secondly, though the medical community must be an integral part in the development of guidelines, funding for this research must be the result of public and private sector cooperation. The ACR is supportive of the funding for this endeavor set forth in the "Medical Care Quality Research and Improvement Act of 1989," and would support additional support through the increased generation of funds by such entities as foundations. The medical community, however, should coordinate the research and development of practice guidelines; through a consortium of universities; non-profit research organizations; or public entities, such as the Institute of Medicine. Congress, the Department of Health and Human Services, and private foundations should all increase available funding for development of practice guidelines.

Thirdly, the issue of how practice guidelines are to be applied must be considered. Various applications have been suggested, but under any system the guidelines must be used as an educational tool for physicians in providing the highest quality of care. Practice guidelines could also voluntarily be used by physicians in examining their own performance. Such usage could be extended as part of the credentialing process.

Practice guidelines might also be used for payment purposes, in determining coverage policy or in determining medical necessity, and therefore payment, for specific services. The ACR would urge that great care be exercised in utilizing practice guidelines for payment purposes, as physicians do not want to find themselves in the position of justifying that a procedure is necessary although it does not meet a payment standard. With appropriate specialist input, however, practices that are extreme, could most certainly be excluded from what would be considered appropriate care.

Medical liability premiums could be reduced through the proper use of practice guidelines. This has already been demonstrated in some states in anesthesiology practice where guidelines have been instituted. Several states have programs in place whereby physicians receive reductions in their liability premiums if they follow established standards. Though it is too early to determine the overall effect on medical liability premiums, there is support for this approach in the medical community.

The many applications of practice guidelines highlight the importance of determining their most effective use. The ACR would urge that examination of appropriate applications occur simultaneously with research and development of practice guidelines.

Finally, as practice guidelines are developed, the ACR urges the Congress and the Administration to coordinate these efforts with other approaches to the pressing issues of utilization, quality, and volume of health care. ACR believes that practice guidelines offer an effective means of ensuring quality care and controlling volume. However, these guidelines can be more effective if developed in conjunction with other measures, such as increased data collection and analysis of outcomes as set forth in H.R. 1692; the development of more effective medical review programs; and reform of the physician payment system. A more comprehensive approach will be of most benefit in achieving the goals of increasing the quality and cost-effectiveness of medical care.

Conclusion

The ACR is supportive of the efforts of the Congress to address the important issues of outcome, effectiveness, and appropriateness of medical care. The "Medical Care Quality Research and Improvement Act of 1989" sets the stage for improved care through funding for research, dissemination of findings, and development of practice guidelines.

Practice guidelines can be a most effective tool in assisting physicians in providing the highest quality of care through the most cost-effective means. The ACR is strongly

supportive of the development of such guidelines with input from the physician community, careful determination as to how they will be applied, and continued efforts in other arenas which will favorably affect the quality and cost-effectiveness of medical care. We specifically recommend that when guidelines are developed for the management of rheumatic diseases, that the ACR become involved in this effort. The College has already initiated efforts in this area.

M-HPS-1307

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of the
American Hospital Association
before the
Subcommittee on Health
of the
Committee on Ways and Means
of the
U.S. House of Representatives
on the
The Medical Care Quality Research and Improvement Act of 1989

June 9, 1989

The American Hospital Association (AHA), on behalf its nearly 5,500 institutional members, appreciates this opportunity to present its views on H.R.1692, the Medical Care Quality Research and Improvement Act of 1989. AHA strongly supports research into the effectiveness of medical care.

The need for effectiveness research is widely recognized. It has long been thought that a significant level of inappropriate, inefficient, or unnecessary services are provided each year. More than a decade ago, epidemiologist John Wennberg, M.D., revealed wide variations in the use of certain medical interventions among comparable populations without a demonstrably different impact on health status. Researchers do not understand why this variation exists, but Dr. Wennberg has suggested that greater variation exists for conditions where there is a lack of consensus among clinicians about what works best. In recent years, using explicit practice guidelines developed by expert panels, researchers have found that large percentages of certain tests and procedures are performed inappropriately, i.e., without sufficient clinical justification. Generalizing from the extant research, some rather extravagant claims have been made about potential savings that could be realized by standardizing practice guidelines for certain interventions and eliminating "unnecessary" or "inappropriate" care.

Under the assumption that large savings would accrue to the Medicare program by eliminating inappropriate care, Medicare has required Utilization Review Committees, Professional Standards Review Organizations, and now Peer Review Organizations to review the care provided to Medicare beneficiaries. Because these efforts have been undertaken without establishing clear standards for what constitutes "appropriate" care, the promise of big savings has not materialized. The lack of standards has kept denial rates relatively low (under 5 percent), but it also has kept frustration levels relatively high among hospitals and physicians.

Above all else, the research reveals how little is really known with certainty about what works best in medical care. Others following Dr. Wennberg have confirmed that although large unexplained variations exist in the utilization of certain services, a significant level of inappropriate care is not necessarily provided in high-volume regions. This suggests that inappropriate care does not explain the geographic variation in utilization rates. Moreover, those who have studied geographic variation concede that they do not know whether the high or low rate of utilization is more appropriate or more beneficial to the population. It may be that differences in these variations may affect the health of the population; to date, however, reserarchers have been unable to develop outcome measures sensitive enough to capture them.

In theory, better defined practice guidelines would result in greater consensus among clinicians and, consequently, less variation. Large cost savings, however, will not necessarily follow.

As little as we know about what works, we know even less about how to go about effecting changes in medical practice. If we do not know the cause of practice variations, how do we go about the process of eliminating them? Assuming that improved practice guidelines enhance our ability to identify inappropriate care, what are the most effective ways of eliminating it? Can it be eliminated simply by improving the indications for treatment and getting that information to clinicians? Will equivocal results with respect to the relative efficacy of different interventions make consensus impossible? To what extent is care that is classified as inappropriate provided because of patient and family perceptions of need? Can this care be eliminated without actions designed to change patient expectations? What are the most effective techniques that hospitals and their medical staffs can use to change inappropriate utilization patterns? And what implications would more explicit treatment guidelines have for the external monitoring of hospitals by PROs? These questions need answers. AHA is working to help hospitals and their medical staffs through the Quality Measurement and Management Project (QMMP) of AHA's Hospital Research and Educational Trust. In addition to developing a model for integrated quality assurance in hospitals, QMMP is developing a data reporting system that can be used by hospital managers to evaluate and improve their own clinical performance.

AHA strongly supports effectiveness research for a variety of reasons:

- It will clarify which interventions work best and under what circumstances (for what patient conditions);
- It will produce clinical practice guidelines or standards of what constitutes appropriate care which will furnish hospitals and physicians with a means by which they can monitor and modify their own performance;
- It will give us a more realistic view of what services can and cannot be eliminated;
- It will help to assure that those who need services will get services; and
- It will provide some guidance for external review mechanisms that now seek in relative ignorance to distinguish the appropriate from the inappropriate.

H.R.1692 would provide a much-needed boost to this exciting and already burgeoning area of research. We have some specific suggestions, however, to help sharpen the focus of this funding effort:

Scope of Research

Sec. 1140(a) would authorize outcome, effectiveness, and appropriateness research. These are defined in Sec. 1140(h) as follows: "outcomes research" is comparative research of the relative effect of different interventions for the same medical condition; "effectiveness research" is research into the effectiveness of a particular technology or procedure, with feedback to refine or improve the technology; and "appropriateness research" is the establishment of practice guidelines to standardize indications for what constitutes appropriate indications for the intervention.

The definition of "appropriateness" ignores an area of research for which there is an equally urgent need. "Inappropriate care" is commonly understood to mean either care which is considered not medically "necessary", i.e. the proper indications for the intervention were not present; or care which is provided inefficiently, in a setting more expensive than is necessary. A great deal of external monitoring by PROs reflects a strategy of shifting the provision of care from hospitals to other less restrictive and perhaps less costly settings. Although criteria for external review to determine the need for inpatient care has been developed, their reliability and validity has not been tested. Using the criteria to screen admissions also raises the question of how screens affect patient health. Even less is known about indications of need for other types of services, which makes it difficult to assure the continuity of patient care following hospital discharge.

The development of practice guidelines will improve PROs' and other external reviewers ability to identify which care is medically unnecessary or not indicated. But even improved quidelines will not address the crucial questions surrounding the appropriate site where services can most efficiently and effectively be provided. We urge that the definition of "appropriateness" research be expanded to address this issue of appropriate service setting and the appropriateness of criteria used for post-hospital patient placement.

Data Base Development

Sec. 1140(b) would require the Secretary to develop standards for data gathering to foster effectiveness research, including the definitions of the information on patient clinical and functional status to be collected, reporting formats, and measures to safeguard the security and accuracy of the information.

The statute states that these standards would apply to data gathering "whether by the Secretary or others." It is unclear, however, whether this refers only to other federal initiatives or to private-sector initiatives as well. By stating that it intends to promote "a wider base of information which can be linked together," the statute implies that the Secretary's standards would apply to all data collection efforts outside of the direct control of HHS. It is unclear how these standards would be promulgated, and what enforcement authority HHS would have for imposing them. The final provision for a report to Congress on the feasibility of linking all federal departmental information suggests, in contrast, that only federal data collection initiatives would be affected. These matters need clarification.

Standardization of definitions is clearly desirable so that information collected by various entities is comparable. More consistent data will make research results more amenable to meta-analysis for overall evaluations of clinical effectiveness studies.

In developing these standards, it is important to take into account data collection efforts that are currently underway. The advisory council created under Sec. 1140(e), could play a useful role in this regard. The role of the advisory council, which would be comprised of researchers, hospital representatives, accrediting body officials, insurers, employers, and consumers, appears limited to the provision of advice and comment with respect to the Department's research initiative. We suggest that the role of the advisory council be expanded to advise the Department with respect to its standards development for data collection as well.

It is unclear whether the true import of Sec. 1140(b) is the standardization of the data to be gathered and reported for research purposes or the authorization to the Secretary of HHS to collect and maintain a data base from providers for research purposes through claims submissions. Several private and public research efforts are now exploring data requirements for the development of indicators of clinical performance and the appropriate risk adjustment of those indicators to make them more meaningful. A careful validation of the costs and benefits of any such system is necessary. In the absence of any clear consensus among researchers about what data are most relevant and what means of risk adjustment are most effective, it would be premature to require the Secretary to specify a minimum clinical data set. Providers, payers, and government should work together toward the development and adoption of a a universal data set that would minimize provider data system conversion and reporting costs while supporting appropriately adjusted outcome indicators.

Education

Sec. 1140(c) provides that some of the funds will be devoted to the dissemination of research findings and the education of physicians to promulgate the practice guidelines and help to standardize medical decision-making.

The statute seems to contemplate two means of promulgating change in medical practice. First, the dissemination of research findings to the physician community. Second, the training of "physician managers within provider organizations." This latter notion is not explained further.

Although it is important to make sure that research findings on effectiveness are promulgated to the field, it would be fruitful to use some of the research funds to explore other means of assuring the appropriateness of care that is provided other than simply disseminating information. Dr. Wennberg in his work in Vermont and his colleagues in the Maine Medical Assessment Project have found that data feedback comparing physician practice patterns along with direct interaction among physicians is an essential prerequisite to changing practice styles.

The "formal training program" for "physician managers" referred to in Sec. 1140(c) suggests some mechanism within hospitals to enhance the ability of hospital medical staffs to use information on outcomes and effectiveness. Absent some better explanation of what is meant by this, we recommend deleting reference to these training programs. Instead, direct the Secretary to explore, through additional research, various ways to accomplish the desired change. What institutional processes are most effective in ensuring that only appropriate care is provided? With better practice guidelines and better criteria, what shape should the Medicare program's external review program take? The answers to these questions are by no means obvious and are fully as worthy of study as the issues of medical effectiveness.

AHA appreciates this opportunity to express its support for H.R.1692, the "Medical Care Quality Research and Improvement Act of 1989." The research funded under this bill could provide answers to some of the most vexing questions about the provision and the regulation of medical care.

STATEMENT OF THE
AMERICAN SOCIETY OF INTERNAL MEDICINE
TO THE
HOUSE WAYS AND MEANS SUBCOMMITTEE ON HEALTH
ON THE
MEDICAL CARE QUALITY RESEARCH AND IMPROVEMENT ACT OF 1989
(HR 1692)

The American Society of Internal Medicine (ASIM) is pleased to take this opportunity to share its views on HR 1692, the "Medical Care Quality Research and Improvement Act of 1989." ASIM commends Representatives Gradison and Stark for their efforts to introduce legislation to establish a national program of research on the outcomes, effectiveness and appropriateness of medical care and to foster the development of practice guidelines.

The Need for Research on Outcomes, Effectiveness, and Appropriateness

A number of factors have converged recently that highlight the need for greater medical research and consensus over what constitutes good medical care. The most notable factor has been the rise in health care expenditures resulting from increasing medical costs and a greater volume of medical services. This increase in expenditures is best represented by the growth of Medicare, where budget outlays have increased at an annual average rate of 15.5 percent between 1975 and 1987. Forty percent of that increase under Part B resulted from a greater volume of medical services, defined as the number of services rendered per beneficiary during a defined period of time. While at this point it is unclear how much of this volume increase resulted from the provision of ineffective services or, on a more positive note, reflects better access to medical care, improvements in patient care and increased patient demand, the increase is symptomatic of the need for better medical consensus on when specific medical services are effective.

This growth in the volume of medical services (and consequently medical expenditures) is especially problematic because wide variations exist in physicians' practice patterns. John Wennberg, MD, has demonstrated through the use of small-area analysis that inexplicable variations exist in the way physicians provide medical and surgical services. Although some variation can be explained by differences in either the patient populations or the medical communities -- e.g. the availability of medical technology, facilities or practitioners -- a substantial part of practice variations are the result of genuine differences in the way physicians believe they can best care for their patients.

Research by Robert Brook, MD, and Mark Chassin, MD, comparing the appropriateness of care under different practice patterns has further complicated the picture by revealing that a certain level of inappropriate care is provided regardless of whether that care is provided in a "low" or "high" use area. For instance, Brook estimates, based on his work, that as much as 17 percent of all coronary angiograms are provided without appropriate indications, regardless of whether they are provided in a low or high utilization area. Findings such as this have highlighted the need for guidelines in helping phsycians determine when to use certain diagnostic and therapeutic services.

When researchers have done extensive literature and data analysis to determine the efficacy of certain services and in what circumstances those services should be provided, they frequently have not been able to make conclusive judgements. Medical research on the outcomes of procedures and services is frequently lacking, inconclusive or conflicting. For example, David Eddy, MD, has compared medical literature on the merits of angioplasty as opposed to bypass surgery and found little conclusive evidence to determine the appropriate choice for patients. Similarly, William Roper, MD, the former administrator of HCFA has acknowledged that medical data has not been adequately collected and examined to determine the outcomes of specific types of care.

Finally, the combination of these factors -- practice variations, inappropriate provision of medical care and inconclusive medical evidence on what is appropriate care -- has raised concerns about the quality and effectiveness of current medical care. Patients, payors and physicians are naturally interested in assuring that the medical care they receive, pay for or provide is of good quality and effective. With little evidence for evaluating these qualities, however, such judgements are highly subjective.

The Issues Around Developing Guidelines

Practice guidelines are increasingly viewed as an important tool for assuring the efficacy of medical services. Proper guideline development requires combining a broad spectrum

of research, including examining practice variations, medical outcomes and appropriateness assessments. These different research endeavors help identify where medical consensus is lacking, determine which treatments are potentially beneficial and then match the appropriateness of specific interventions with specific indications. Since this research cuts such a broad swath, a number of issues have emerged concerning the practical value of guidelines, how they should be developed, who should develop them, and how they should be used once they are developed. These questions (and answers) were best framed by Mark Chassin, MD, in his paper "Standards of Care in Medicine" and several of them deserve consideration by the Subcommittee.

Can the use of standards improve medical practice? Since numerous standards already exist and are used in various ways, some individuals wonder whether standards actually have any practical value. They argue that each patient is unique and that scientific research is so dynamic that meaningful guidelines cannot be developed. ASIM supports Chassin's view, however, that standards can improve medical care but that their success depends largely on how those standards are imparted to the medical community. Simply distributing guidelines to physicians is not effective because there is not sufficient stimulus to encourage a significant and lasting improvement in practice. On the other hand, unilaterally imposing guidelines on the medical profession, especially for payment purposes, is likely to be resisted by the medical community as being suspect. To be most effective, guidelines need to be 1) well-constructed (unambiguous) and scientifically based on areas where there is broad clinical consensus; 2) provided to physicians (preferably face-to-face) by a preeminent physician in that particular medical area; and 3) followed up with data that provides physicians with feedback on how such standards have affected their practice.

Who should develop standards of care? This question includes two specific parts: 1) who should fund or sponsor the development of standards and 2) what individuals and/or institutions should be part of the team that actually develops the content of standards? Guideline development needs to be funded both through the public and private sectors. Although foundations have contributed some money toward guideline research, they have been reluctant to commit a large amount of resources to this endeavor. Further, because of the enormous amount of money required to develop practice guidelines, it is unreasonable to believe that the medical community can obligate itself to the entire cost. Therefore, it seems inevitable that the public will have a major role in funding such outcome studies, especially since it is the public which will benefit from the development and use of guidelines.

Such projects, however, cannot be primarily a federal function. Although the federal government can contribute funds, the research will need to be coordinated by the medical community: a consortium of universities equipped to do this kind of research; private, non-profit research ogranizations; and other public entities like the Institute of Medicine Further, practicing physicians and other health care practitioners need to be integrally involved in developing these guidelines. Standards development should not be restricted simply to physicians in academic settings or those physicians most specialized in a specific condition. Rather, generalists and other practitioners who provide care to those patients should be part of the guideline development.

How should standards of care be used? The use of practice standards is probably the most polemical issue in developing guidelines. The most widely accepted use of standards is as an educational tool that guides physicians in patient care. A related educational use of guidelines would be to allow physicians to use guidelines on a voluntary basis to test their performance. For instance, the Canadian Association of Family Practitioners has such a program that allows physicians and hospitals to evaluate their performance. An extension of such an application would be the use of guidelines as part of the credentialing process, whereby physicians' practice patterns would be used for granting privileges.

Another application of standards (and more problematic) is their use for payment purposes. For instance, practice standards can be used for determining coverage policy. If certain indications are deemed ineffective for a given procedure, a payor may preclude coverage of that procedure in its policy.

A related but significantly different application would be the use of standards for determining medical necessity and therefore, payment for specific services. Under such guidelines, a standard could be used for determining whether or not further review of that care is warranted and ultimately whether payment should be made for those services. Such an application is more bothersome for physicians, however, in that it implies that a procedure is unnecessary if it does not meet a payment standard.

A new application of standards has been for reducing medical liability premiums. For instance, in Massachusetts anesthesiologists receive a reduction in their liability premiums if they follow standards established by the Massachusetts Medical Practice Joint Underwriting Association. A similar incentive has been used in Oregon for family physicians who use established obstetrical guidelines. While such applications are still too new to make a proper assessment of their full ramifications, physicians have responded favorably to the use of standards in this way.

Finally, standards could be used by consumers in at least two ways. Consumers could use standards to determine the necessity and efficacy of the care they receive. Most patients, however, would not be predisposed to use standards in this fashion. Standards also could be used by patients in choosing what practitioners and/or providers they wish to use. Such an application is doubtful unless the Medicare program would use standards in evaluating physicians' care.

While the need for practice guidelines is apparent, the medical community, as well as others, need to more carefully examine the best applications of guidelines. For guidelines to be effective, they ultimatley will not only need to be medically sound, clear and concise, but also applied to medical practice in a way that facilitates their use rather than generates doubt, suspicion and resentment. Therefore, the examination of how guidelines can be effectively used should occur simultaneously as research on actual guideline development progresses.

Recommendations on HR 1692

ASIM believes that the "Medical Care Quality Research and Improvement Act of 1989" sets the stage for improved care through funding for research, dissemination of findings, and development of practice guidelines. Since developing guidelines is the best long term approach to reducing the volume of ineffective servics, and since large gaps remain in our knowledge about the effectiveness of medical services in terms of outcomes, there needs to be a substantial, coordinated effort by the public and private sectors to determine what comprises high quality, cost effective care. We believe that the federal government's role should be to act as a catalyst for this research and to provide guidance on how such research should be conducted. Although the federal government should contribute funds to these research projects, the research should be done by entities that have credibility with the physician community. Consequently, HR 1692 should direct the Secretary to specifically provide funding to entities such as representative medical organizations, universities equipped to do this kind of research, private, non-profit research organizations, and other public entities like the Institute of Medicine.

We also urge you to delete sections of the bill requiring practice guidelines be developed by the Secretary. A more appropriate role for the Secretary of HHS should be to oversee the development of practice guidelines, by providing funding to medical organizations and other entities to actually develop the guidelines. We also recommend that the language in Section 1140 concerning the appointment of members to the advisory council overseeing the development of the guidelines be clarified to specifically require inclusion of practicing physicians on the council and consultation with medical specialty societies in identifying potential nominees. In addition, Section 1140 should include language to provide for consultation with the medical community when setting research priorities with respect to specific medical conditions and treatments to be studied.

When choosing the diseases and treatments to be studied, HR 1692 should give more explicit direction to the Secretary to give immediate attention to researching and developing practice guidelines for "high volume" services reimbursed under the Medicare program, since that would be the easiest area to initially devise clinically sound guidelines and could provide significant savings if practice patterns were corrected. For instance, each year Medicare spends over $300 million on coronary bypass operations. If just 10 percent of these procedures are ineffective and were corrected or detected through the use of guidelines, Medicare could save more than $30 million.

Knowledge gained from creating procedure guidelines should be used later for developing more complex and difficult "patient problem" guidelines. Information accumulated through the use of the guidelines also should be used to determine the efficacy of indications that initially are considered equivocal.

In the dessemination of practice guidelines, the Secretary should ensure 1) the continued ability of physicians to exercise judgement to deviate for good cause from the protocol in a given case; and 2) a commitment to continually reevaluate the data base and the resultant protocols, to keep pace with medical innovation.

As the committee is aware, the chairman of the Energy and Commerce Subcommittee on Health and the Environment is introducing legislation in the next few weeks to facilitate and promote outcomes assessment research and the development of guidelines. ASIM has been working with the bill's sponsors, and believes the legislation represents a sound approach to promoting outcomes assessment research and guidelines development. We urge this Committee to work with the sponsors of this bill to develop a consistent statutory approach on this important issue.

Finally, Congress and the Administration should coordinate their efforts in guideline development with other activities (data collection and analysis, medical review and physician payment reform) that can help immediately address issues around the utilization of medical care. In February, ASIM published a 14 point plan for "Controlling the Volume of Ineffective Medical Care" that advocates a comprehensive effort among the medical community, Congress and the Administration in addressing concerns over the volume of medical services. Although there are several viable options for addressing the increase in medical volume, there is no single, easy method -- including the use of guidelines -- for solving this problem. Therefore, ASIM is promoting a more comprehensive approach to this issue through 1) increasing data collection and analysis; 2) developing more effective medical review programs; 3) reforming physician payment; and 4) developing appropriate practice guidelines. Attached to this statement is the Society's comprehensive set of recommendations.

Conclusion

ASIM strongly supports the efforts of Congress to promote outcomes assessment research and to foster the development of practice guidelines. The "Medical Care Quality Research and Improvement Act of 1989" sets the stage for improved medical care through funding for research, dissemination of findings, and development of practice guidelines. Practice guidelines are potentially an effective tool for assuring the provision of high quality, cost effective health care. ASIM's recommendations for developing practice guidelines establishes a firm foundation upon which this work can proceed. Since practice guidelines are a relatively new phenomenon, however, caution should be exercised in both developing and applying protocols of care. The inclusion of the broader medical community in this project, along with adequate direction and funding are two particularly important elements in creating sound practice guidelines.

In addition to outcomes assessment research and guidelines development, other research and review activities should be used to supplement and complement protocols as a way of controlling the volume of ineffective medical care. Specifically, increasing data collection and analysis, developing more effective medical review programs and reforming physician payment should be part of this comprehensive approach to increasing the efficacy of medical care.

We welcome the opportunity to work with the Subcommittee in the future on this important issue.

[ATTACHMENT WILL BE RETAINED IN THE COMMITTEE FILES]

TESTIMONY TO THE RECORD OF THE SUBCOMMITTEE ON HEALTH,
COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES,
MAY 24, 1989 HEARING ON H.R. 1692,
THE MEDICAL CARE QUALITY RESEARCH AND IMPROVEMENT ACT OF 1989

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THE NEED FOR OUTCOMES RESEARCH TO INCLUDE POPULATION LEVEL STUDIES OF EPIDEMIOLOGICAL RISK FACTORS, AND THE IMPORTANCE OF LINKING OUTCOMES RESEARCH FINDINGS TO PHYSICIAN REIMBURSEMENT

INTRODUCTION

This bill, H.R. 1692, is a manifestation of rising concern over the increasing proportion of national expenditure absorbed by health care. The expense concerns the public because they are skeptical that they are getting a worthwhile return on their investment.

The bill calls for increased funding of medical care outcomes research to ascertain the value of medical interventions. This information is intended to help policy makers, patients, and providers make medical care decisions.

To ascertain the value of medical interventions, one must answer two questions:

a. How much of the increased survival of Americans is attributable to medical care?

b. How much does medical care reduce the prevalence and degree of disease and suffering?

These two questions need to be considered together because the isolated answers are likely to appear paradoxical. It should not be surprising if it is found that the ambient level of disease and suffering (disability and discomfort) actually increases with increasing medical care expenditure: increased survival attributable to medical care is likely to have a heavy burden of disability and discomfort.

It is popularly postulated that there are diminishing returns on each additional medical care dollar spent, when measured in terms of increased survival and reduction of disease. If this is true, then proportionately greater weight should be given to the competing claims for those dollars.

The goal of medical care is to maintain and restore good health. However, many factors that are contributory to good health are not conventionally considered to be part of our medical care system. Knowledge of those contributory factors is important for health, because they often can be manipulated through individual and public choices to bring about health changes. The goal of optimizing health can only be achieved through attention to all factors that are contributory to health status. The most cost effective interventions may lie outside the domain of conventional medical care: to meaningfully ascertain the value of medical care, it is crucial to consider these alternative interventions.

Known factors that are contributory to health status, yet are not conventionally considered to be part of our medical system, are the known epidemiological risk factors. There are four broad categories:

a. Socioeconomic status (SES). This is the single most important predictor of health status at the population level. Clearly there is some interaction with the remaining epidemiological risk factors, as there is with access to quality health care. The three major components of SES are income, education, and occupation. SES is conventionally regarded as near constant for individuals; however, this conventional approach may not be appropriate, because income

and occupation can change sharply with changes in the economy and personal health. It can be seen that factors such as welfare payments have an important influence on the SES of large sectors of the population, and can be directly and swiftly manipulated through policy changes - with ensuant changes in health status.

b. Consumption factors. Saturated fat, tobacco, and alcohol consumption are well documented to be causally related to cardiovascular and cancer death and morbidity. The patterns of consumption are intricately linked to SES.

c. Psychological stress. The degree to which a given stressor has adverse health effects is a function of the individual's human, material, and personal resources - which are all highly correlated with SES; further, the extent to which any individual is exposed to stressors is also a function of SES. It would seem a reasonable hypothesis that psychological stress, and therefore the health, of large sectors of the population, is exquisitely sensitive to social and economic factors such as the levels of unemployment and the level of welfare spending.

d. Toxic chemical exposure. Environmental and workplace toxic exposures have many adverse health effects, of which cancer is the most important. Again, there is a strong correlation with SES through such factors as real estate prices (place of abode) and occupation. At the population level, the degree of exposure is sensitive to regulation and education.

Many of the findings from outcomes research, especially those that emanate from epidemiologic studies, have their most direct applications at the policy, rather than the clinical, level - e.g. deciding the size of health care budgets, and deciding the directions which health promotion campaigns should take. These are important benefits from such research, but there are also benefits which are directly applicable to clinical practice.

There is a need for innovations within clinical practice in order to apply the information being gained on both long term health outcomes and the interventions that have measurable health effects only when large populations are studied. The traditional client-initiated medical encounters are not adequately responsive to the wealth of information now becoming available. Individual members of the public cannot reasonably be expected to seek care and advice in a manner that is timely for optimal health. Additionally, providers are responsive to factors that are not necessarily consistent with the optimal health of their clients.

We suggest that one such innovation is to structure the payment of physicians such that there is financial incentive to provide optimal care. This could be achieved by making the highest priority interventions the most profitable, and lower priority interventions correspondingly less profitable. The advantages of such a system extend beyond the day-to-day practice of medicine: it would stimulate a keen interest in outcomes research, it would provide a framework for the practice of preventive medicine, and it would help disseminate the most significant medical information - even amongst the most avaricious of medical practitioners. Adherence to medical practice guidelines would become financially rewarding, and thus one would expect that practices would become more standardized.

BACKGROUND

There are two principal approaches by which health professions ordinarily seek to influence health and longevity: medical care and health promotion activities. The traditional body of medicine and surgery supports the health services approach while the epidemiological literature supports the health promotion effort. However, the classic question remains as to whether medicine and surgery make a significant contribution (particularly in light of the resources expended) to the reduction of infectious and chronic disease morbidity and mortality. Important questions have also been raised, recently,

as to the efficacy of health promotion activities.

This problem is complicated because, in order to evaluate outcomes of health care changes in populations, the epidemiologic risk factors affected by health promotion efforts must be simultaneously considered - and vice versa. However, the research fields of epidemiology/health promotion and health services have historically been separated in such a manner that research in one particular arena does not usually deal with variables pertinent to the other. Equally important, neither field usually takes into account SES, the most important epidemiologic risk factor and one which dramatically influences health care outcomes. Nor do they take into account changes in the macroeconomic environment that influence SES change. Additionally, the health promotion and intervention studies do not consider overall changes in societal consumption and production patterns occurring in the macroenvironment. Finally, rarely do health services or epidemiologic and health promotion evaluations deal with the lengthy lags (e.g., 5-10 years) required for observation of morbidity and mortality outcomes.

Medical Care

The contribution of medical care to the decline in overall mortality that has occurred in the United States since 1900 has been questioned[1]. Even if consideration is restricted to the decline in the period between 1900 and 1950, which was due mostly to the virtual disappearance of several major infectious diseases, it has been argued that the contribution of medical care was minimal[2,3]. It has been estimated that, at most, 3.5% of the decline in the overall death rate between 1900 and 1973 can be explained by medical interventions for the eleven major infectious diseases considered[3].

Since the beginning of this century there has been a change in the relative contribution of infectious disease and chronic disease to total mortality. Proportionately far more people have died of chronic disease in the post-war period, thus, if medical care has made a substantial contribution to the decline in mortality in this time, then the effect must have been made in the chronic disease arena.

The three leading causes of death in the post-war period have been diseases of the heart, cancer, and cerebrovascular disease. The trends in mortality for these disease groups varies on a disease-specific basis. Death rates due to heart disease have dropped sharply since 1968 for both sexes and all races[4,5]. Cancer death rates have been increasing for both males and females, mostly attributable to respiratory cancer[4,5]. Stroke has been the third leading cause of death, but in 1985 accounted for less than 8% of all deaths, while heart disease and cancer combined accounted for almost 60%[5].

The reasons for the decline in heart disease mortality are thought to include lifestyle changes (reduced smoking, diet changes, increased exercise) and improved medical care (control of hypertension, treatment of heart disease, access to coronary care units)[5]. The decline in coronary heart disease mortality coincides with improvements in both medical care interventions and pharmacological treatment for known risk factors[6,7].

Researchers have attempted to quantify the portion of the decline in coronary heart disease mortality that can be attributed to the use of medical care. By applying the calculated benefits from clinical trials, it has been reasoned that approximately 38% of the decline in coronary heart disease mortality that occurred between 1968 and 1976 might be attributed to medical care measures, leaving more than 60% of the decline to be explained by other factors[8].

Cancer death rates have been increasing in the post-war period, largely attributable to the increase amongst males[9]. Increased mortality rates for respiratory cancer has elevated the all-cause cancer death rate trend[5]. Medical care for lung cancer appears not to have appreciably affected the mortality rate. Medical intervention (chemotherapy and radiation treatment) have been effective against some forms of cancer but those forms

comprise a small portion of the total incidence[10]. It is argued that, overall, medical care has been relatively ineffective against cancer mortality[1].

Stroke mortality has declined substantially since 1945[5]. The increased use of antihypertension drugs has been cited as a major reason for the decline in stroke mortality occurring since the early 1970's[11]. However, at most, 38% of the decline can be explained by improved medical management of hypertension[1]. The causes of the large decline in stroke mortality are not well understood[5].

There are important limitations to these studies of the health effects of medical care. Generally, the studies have used undifferentiated populations and no control variables. When the analyses have been disease-specific, the particular populations at risk have not been specified. Under these conditions the benefits of medical care may be masked by social, environmental and behavioral factors[12]. In addition, inappropriate criteria may have been used to measure the effectiveness of medical care. It has been argued that mortality is not the correct criterion, but rather morbidity levels, quality of life measures, and level of functioning are the standards against which the contribution of medical care should be judged[13,14]. Cross national study has shown that the major determinant of physician use is in fact perceived morbidity[15]. Medical care consumers must draw some satisfaction from the use of the service (even if it is only peace of mind), because repeated use is typical.

When morbidity rather then mortality data is used as an indicator of health status a different picture is seen. In 1984, the five major causes of death account for 76% of all mortality. However, those five major causes of death account for less than 50% of short-stay hospital discharges and less than half of all physician visits[1].

Indirect measures of morbidity and illness have been used to determine whether the health of the nation is improving. Three such measures used are work loss days, restricted activity days, and limitation of activity.

The trend over the past thirty years in work disability has been examined; while the investigator cautioned that there are exogenous factors which may bias the data, he concluded that the increase in work disability prevalence rates are real[16]. This may be secondary to the age-adjusted decline in mortality[1].

The rates for restricted activity and bed disability days have been increasing since the late 1960's[4]. These trends may reflect actual increases in morbidity or they may be due to persons limiting their activity at the onset of illness in order to prevent more serious consequences. It has also been suggested that the trends correlate with increased physician use during the same time period and may reflect earlier illness detection and better health management, or an increase in doctor-prescribed rest days[17,4].

Limitations of activity due to chronic illness have been increasing during the past two and a half decades[1]. A portion of this increase has been attributed to administrative changes in disability benefit programs which permitted earlier retirement on disability grounds[17].

The index measures of morbidity, discussed above, suggest that morbidity has not been declining during the past twenty to thirty years. Some authors have argued that medical care may be an important factor in <u>increasing</u> the prevalence of disability by increasing the survival of individuals but leaving them in a disabled condition[1].

Studies are required that, on a population basis, can explain the observed changes in morbidity and mortality trends and account more fully for the contribution of medical care to these trends. These studies need to be capable of comparing the role of medical care with the roles of environmental, economic, epidemiologic, and social factors in advancing the health of Americans.

Health Promotion

The major objective of epidemiologic studies is the identification of risk factors which are associated with specific diseases and which can be modified. The reduction, modification, or elimination of such risk factors could then prevent the occurrence of the disease or favorably alter the course of the disease through early detection and treatment.

During the past thirty years, an impressive body of knowledge has been gathered regarding risk factors for the three leading causes of mortality: heart disease, cancer, and stroke[18,19,11]. Three major risk factors for coronary heart disease (CHD) have been identified and targeted for intervention programs: high blood pressure, elevated blood cholesterol levels, and cigarette smoking. Other risk factors which are known to be associated with CHD include physical inactivity, type A behavior, nondrinking or heavy drinking of alcoholic beverages and low socioeconomic class. The predominant risk factor for stroke is high blood pressure, although clinically evident diabetes and heart disease are also important.

Cancer epidemiology is a more complex field. Major risk factors include high fat, low-fiber diet and ethanol consumption (colorectal cancer); cigarette smoking, exposure to industrial substances (uranium and chromium), asbestos, and air pollution (lung cancer); and family history of breast cancer, early menarche, late menopause, nulliparity, first birth after age thirty and diet (breast cancer)[19]. Cessation of smoking, alteration of diet, and minimization of carcinogenic agents in the environment are the major tools available for reducing the incidence of cancer.

Health promotion activities, the application of health risk information, take place at three societal levels. At the individual level, person to person counseling takes place in physician offices, clinics, and hospitals in addition to other settings. Community level health education campaigns address relevant health information to community groups, school groups, and the general public using brochures, lectures, support groups, and media sources. The national level is reached via the mass media which reports the latest results from scientific studies, as well as public statements and reports released by professional and governmental organizations. The goal of these efforts is to encourage individuals to adopt healthier lifestyles, and the results can be measured by studying the consumption trends for products and substances which have been the target of the health promotion activities (e.g., alcohol, cigarettes, saturated fats).

The main focus of health promotion campaigns in the last decade has been to reduce the prevalence of smoking, to change dietary habits so as to reduce blood lipid levels (eat fewer foods that are high in cholesterol and saturated fats) and reduce the prevalence of high blood pressure (eat less salt and saturated fats). These recommendations would seem to be well grounded on current epidemiologic knowledge; however, in recent years, the validity of these health promotion campaigns has been questioned. It is argued that there is no experimental evidence that intervention programs prevent coronary heart disease or reduce overall mortality; further, epidemiologic studies can illustrate associations between risk factors and disease, but only experiments can prove causality[20,21]. Since some experimental studies have failed to show a statistically significant reduction in either coronary heart disease mortality, or overall mortality the critics conclude that reductions in risk factors have had no effect and question the continued expenditures on a crusade which lacks scientific basis[21].

These criticisms of health promotion activities strengthen the case for health outcomes research conducted at the population level, and for techniques that extend the capability of traditional intervention-observation trials. To explain trends observed at the population level, the analysis should be conducted at the population level. The extrapolation of relationships observed at the individual level onto the population may suffer greatly from problems of aggregation bias

relating to major shifts in the population prevalence of epidemiological health risks. This also allows for consideration of the macroenvironment in which the intervention studies are embedded. This environment has affected the results of those studies, as well as observed secular trends for the entire population. Factors ignored in the above studies include: the diffusion of knowledge regarding health risks to the entire population via the mass media, the SES of population groups and the impact of changes in the economy on SES of specific populations[22,23,24]; changes in the level of environmental contamination from chemical toxins which have been implicated as causes of malignancies, metabolic disorders, and respiratory diseases; and changes in family structure which disrupt established social support patterns[22,23,24,25]. These factors, particularly when considered together, can fundamentally alter the outcomes of health promotion efforts. Additionally, studies must adequately take into account the lengthy lag times between interventions and effects, and the study group must include the age at which one would expect to observe the effect.

Preventive Medicine

Preventive medicine is practiced at many levels; it includes much of conventional medical care, and it includes health promotion activities. What is not generally recognized, in this country, to be a part of preventive medicine, is the economic well being of individuals. This is a paradox, because it is part of the conventional wisdom we impart to health workers in the third world[26]. This conventional wisdom is equally applicable in the U.S. As indicated in the introduction, SES is the most important epidemiological predictor of health status, and it has a pervasive effect on the three other major categories of epidemiological risk (consumption factors, psychological stress, toxic exposure) as well as on access to quality health care. At the population level, the health of individuals is influenced by both their absolute and relative economic well being. In this regard, welfare spending (in its broadest sense, which may include job training etc.) should be viewed as preventive medicine. Further, extravagant or wasteful spending on medical care may divert money from those welfare portions of Health and Human Services budgets which may have more important effects on health.

A premium on cost-effective medical care

For the state-of-the-art in cost-effective medical care to be standard practice, there need to be innovations within the patient-provider encounter. There needs to be a way of encouraging, not only the most cost-effective traditional medical interventions, but also the most cost-effective health promotion activities.

One suggestion is that third-party physician payment should be structured such that a premium is paid on the most cost-effective components of medical care. This means manipulating the profitability of each medical intervention, according to priorities established with the help of outcomes research. The basis for reimbursement is shown algebraically by the following two equations:

$$R = C + P$$

$$P = F(E,S,1/C,N)$$

where:

R = Reimbursement
C = Cost = legitimate overheads (including training)
P = Profit margin per unit time
F = Function of
E = Effectiveness
S = Skill (independent of credentials)
N = Need at the population level; this is an expression

of such factors as:
- Health Cost & Health Care prevented
- Productivity gained
- Mortality reduced, Longevity gained
- Independence gained
- Societal values

The first equation shows that only the after-costs margin of profit of an intervention is to be manipulated, i.e. reimbursement would be paid for any approved medical intervention at a level that should cover all legitimate overheads, but the amount of additional payment beyond this level would depend the priority of that type of intervention. The second equation indicates the factors that should be taken into account when adjusting the margin of profit, where it is assumed the profitability will act as an incentive/disincentive. The nature of the function in the second equation can be adjusted to achieve the desired outcome. At the simplest level it would be linear - and that is a workable starting point.

The inclusion of population need in the equation is extremely important. The sum of what is best for each individual can be expected to be more than the available resources, so there needs to be some restriction on which medical interventions are made available from communal funds. Further "what is best for the individual" is itself considerably removed from the individual's preferences: preferences are a reflection of individual perception of options available and individual knowledge; the public's welfare is a function of the fulfillment of optimal wants[27]. The inclusion of population need makes the algorithm responsive to long term health status objectives. It means that the best scientific judgement regarding medical care priorities, both curative and preventive, are incorporated into medical practice. It is not restrictive, because it does not forbid deviation from the state-of-the-art in cost-effective medical care, it merely makes such deviation somewhat less remunerative.

Provisional, but operational measures of effectiveness for each medical intervention could be generated quickly by convening panels of experts from each of the specialty groups. We believe that existing medical knowledge is sufficient to assign these interventions crude but operational categories: highly effective, moderately effective, marginally effective, minimally effective. (This process is essentially one of triage at the societal level.) As with all political decisions, value judgments are made on the basis of the available information - no matter how sketchy. The medical interventions should be categorized in terms of their effect on overall patient health status. The medical interventions would also be ranked in terms of their relative effect as a validity check (to avoid the potential claim that all interventions by a specialty are highly effective). This validity check would have the effect of forcing each specialty to single out its least effective interventions.

In the long term, it will not be sufficient to list factors relevant to health status and to present comparative scores in these items when evaluating alternative interventions; nor will it necessarily be appropriate to leave the evaluation in the hands of the relevant specialty groups. The questions arise: important to whom? Should it be the general population? Or just the population immediately affected? Or some other sub-population (such as payors)? Both information on the general population and on those immediately affected (the patients) should inform the final decision process. Although more general (societal) considerations (such as cost) are likely to be discounted in the face of pressing individual need/desires, patient information is important because opinion may change in the transition from hypothetical to actual illness. On the other hand, population level information provides a backdrop of the ambient values. A comparison of the two perspectives, general population versus affected population, should help delineate areas in need of special attention in the final decision process. (Kaplan & Anderson (1987) have attempted this in their "Human

judgment studies"[28]).

The composition of the panels which make recommendations on these issues is critically important. Considerable research has been done on the structure of consensus development conferences[29,30], and there are two important findings that are in the spirit of this discussion: the selection of panelists needs to be consistent with democratic process[31,32], and institutional political influence needs to be checked[33].

RECOMMENDATIONS

1. Commit to research, at the population level, into how much of the increased survival of Americans is attributable to each component of medical care, and at what cost.

2. Commit to research, at the population level, into how much each component of medical care reduces the prevalence and degree of disease and suffering, and at what cost.

3. Commit to research into methodologies to set priorities for medical care interventions, and to put medical care interventions in the context of other social and economic interventions that have important health effects.

4. Commit to the study and development of consensus panels such that they have representation that is consistent with the American democratic process.

5. Commit to the study of third-party payment of premiums to encourage physicians to practice the state-of-the-art in cost-effective medical care.

DISCUSSION

Medical care decisions, at both the policy and the individual levels, are judgement calls - made on the basis of the best available information. We will never have perfect information, but we can strive to use all the information that we have, and can commit to the improvement of our knowledge base. To defer decisions because "more study is needed" is a slippery slope. We believe currently existing methodologies are sufficiently developed to proceed now to establish medical care priorities and to institute physician payment incentives for the practice of the state-of-the-art in cost-effective medical care.

The current review of physician payment represents a unique opportunity to shape the practice of medicine with the future health status of all Americans in mind. Our system of health care delivery needs to be responsive to the best clinical and epidemiological information we have: it would be a regrettable mistake to allow our current fee-for-service oriented reimbursement system to be replaced by the "cost-plus" resource-based relative values scales system with which the Physician Payment Review Commission appears enamored[34]. Such a system has no provision for the shaping of medical care in response to its long term effect on health status.

The commitment to direct incorporation of the best clinical and epidemiological information into medical practice, in the continuing and tangible way we suggest, will give outcomes research the momentum it deserves.

The improvement in health status, for a given level of medical care expenditure, which can be expected from promoting the practice of the state-of-the-art in cost-effective medicine is only part of the benefit provided by outcomes research. Outcomes research that compares the influence on health status of medical interventions with social, economic, and environmental interventions will help in the determination of what the level of medical care expenditure should be. For the advancement of the health of Americans, it is imperative that there be attention to the cost effectiveness of medical interventions - because many of the non-medical alternatives for those expenditures have important positive effects on health status.

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EBRI

U. S. House Committee on Ways and Means
Subcommittee on Health
Hearing on H. R. 1692
The Medical Care Quality Research and Improvement Act of 1989

May 24, 1989

Written Statement of

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This statement is written in an effort to help the Committee assess the need for The Medical Care Quality Research and Improvement Act of 1989 (H.R. 1692). Below it is argued that the inability of consumers, payors, and providers of health care to assess quality of care is a major contributor to health care cost inflation. Without objective information evaluating alternatives, medical treatments are adopted on the basis of provider preferences, aggressive marketing, or unsuitable criteria (i.e., "If it costs more it must be better."). There presently is little economic incentive for providers to practice cost effective medicine in large part because purchasers of health care services can not differentiate low (high) cost providers from low (high) quality providers.

Research into the outcome, effectiveness, appropriateness, and other aspects of the quality of medical treatments is needed not only to promote good health care, but also to assure the efficient functioning of the market for health care services. Quality assessment must go beyond merely determining the efficacy of a given procedure, it must also determine the efficacy of the procedure relative to its alternatives. This is important regardless of how health care is financed, but if we are to continue to have a private health care delivery system we must provide information which allows individual purchasers of health care to weigh the costs and balances of their health care choices.

A public-private partnership is needed to finance, perform, and disseminate the results of research on the measurement of the quality of health care services. The private sector cannot supply all the needed information alone. Utilization review firms which presently review the existing literature for information of this kind are reluctant to share this information even with providers whose cases they are reviewing: it is their stock in trade; their investment. In order for the market for health care services to function properly this information must be widely available. Moreover, the concepts and terminology of this research must be standardized so that all participants are speaking a common language and the results from one project can be directly compared with results from another. The public sector can, and should, help achieve this objective.

The remainder of this statement reviews the causes of health care cost inflation, the measurement of health care quality, and the need for research on quality measurement.

Health Care Cost Inflation

National health care expenditures rose by 8.5% in 1986 and 9.8% in 1987. The United States now spends over 11.5% of its Gross National Product (GNP) on health care. The effect of health care cost inflation is similar to a tax on labor. In the long run, most economists agree that labor bears the full burden of health care cost inflation; in the nearer term employers face higher labor costs and lower returns on investments due to health care cost inflation. Health benefits have grown into a major component of labor costs; in 1970 health benefits comprised 2.4% of total compensation and 23% of total benefits. By 1987 health benefits accounted for 5.4% of total compensation and 33% of all benefits.

Public and private purchasers have adopted a number of health care cost management initiatives in an attempt to restrain the growth in their health care costs. The stated goal of these initiatives is to restrain costs without reducing the quality of care. All health care cost management strategies are therefore attempts to correct for the failure of the market for health care. Health care costs will continue to rise for a number of reasons

including the changing demographics of the workforce, the labor intensive nature of health care services, and the introduction of new technology, even if the market for health care services functioned perfectly. The market for health care services fails in that the mix of services provided is not necessarily the mix fully informed consumers would wish to purchase, and the services provided are not produced at minimum cost.

The failure of the market for health care services is the inability of consumers of health care to evaluate the quality of the services they purchase. The widespread availability of health insurance coupled with the characteristics of the provider reimbursement policies of private and (since the introduction of Medicare) public insurers has reduced or eliminated the incentives to weigh the benefits of common procedures and practice patterns against their costs. The result is that new technology is introduced with little or no evaluation of its benefits relative to costs. Providers adopt practices based on personal preferences. Patients lack the information necessary to evaluate the quality of care they receive before, during, or after an episode of illness. Medical researchers have had little or no incentive to assess the relative benefits of the procedures they developed; to be adopted, new procedures did not have to be more effective or less expensive than existing procedures.

Medical research has produced a rapid expansion in treatment options without concurrent research on the relative efficacy of each option. This has prevented the formation of a medical consensus on the proper treatment of a given set of symptoms. It has been well documented that large variation in practice patterns exists among physicians practicing in the same geographic area[1]. The paucity of research on medical outcomes results in the practice of medicine as an art rather than a science. Malpractice proceedings, which are intended to punish incompetent providers, instead force lay juries to decide the appropriate medical practice for a given condition. The threat of malpractice suits may lead physicians to perform more procedures than they deem necessary or cost effective. Reynolds, Rizzo, and Gonzalez estimate that the combined costs of malpractice insurance premiums, settlements and defensive medicine may be as high as $14 billion per year.leading some physicians to stop performing some high risk procedures.[2]

The sources of health care cost inflation relate back to the allocation of risk. Tax policy not only encouraged the spread of health insurance, but aided the accommodation of health care cost inflation as employees were pushed by general price inflation into higher marginal tax brackets. The spread of health insurance and the characteristics of health insurance in which the insurer bears the risks associated with the uncertainty in the efficacy of treatment, increased the demand for health care services and stimulated the development of new procedures. Hospitals and physicians in competitive markets are quick to adopt new technology, raising their costs. Providers, given a longer list of potential procedures that could be performed for a given condition, provide more intensive and more specialized care. The increased costs of health care services increases consumer demand for health insurance.

Cost management strategies can be viewed as attempts to limit moral hazard and to force patients and providers to assess the expected cost and benefits of each treatment decision. The benefits of care and the quality of care

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[1] For a good review of the evidence see Wennberg, John, and Alan Gittelson, "Variations in Medical Care among Small Areas" *Scientific American*, Vol 246 (1982) pp: 120-135

[2] Reynolds, Roger A., John A. Rizzo, and Martin L. Gonzalez, " The Cost of Medical Professional Liability" *The Journal of the American Medical Association*, 1987: 257; pp: 2776-2781

are clearly related concepts. Viewed in this way it becomes clear that health care cost inflation and health care quality are inseparable issues. All effective health care cost management strategies must assess the quality of health care.

Health Care Quality

Defining and measuring health care quality are controversial and costly endeavors. Quality of care is a multidimensional concept: it can be viewed narrowly (as clinical effectiveness) or broadly (as all the attributes of medical care that patients value). The difficulty with any multidimensional concept is weighting the disparate components. Even if individuals agree on the attributes of care that determine its quality, they may disagree about the relative importance of each attribute. While any definition should include the efficacy of treatment its importance relative to other components of quality is subjective.

Third party payers are beginning to use a definition of quality care that, at least implicitly, requires not just that care be efficacious but also cost effective. In a sense, if two treatment regimes provide the same level of patient satisfaction and yield the same outcomes, the lower cost treatment is judged to be higher quality. Utilization review is an example where the payer determines quality care as the least expensive care.

Measuring health care quality is at least as difficult as defining it. Donabedian classified attempts to measure quality of care as studies of structure, process, and outcome.[3] Structure refers to the attributes of care: the qualifications of the care givers, the resources available at the site of care, and other attributes. Evaluation of the process of care examines the activities of care givers, the decisions made at each step in an episode of illness, and the appropriateness of the care provided. Outcome measures the effects of care on health status and patient satisfaction.

These measures of quality are interrelated. As Donabedian and others[4] have pointed out measures of structure and process are only important as indicators of quality if they are related to outcomes, and measures of outcomes are important only if they can be related back to the structure and process of care, and not to environmental or other factors.

Structural measures of quality have historically been employed in the various accreditation processes used by both private agencies (the Joint Commission on the Accreditation of Health Care Organizations (JCAHCO) for example) and public agencies (such as the Health Care Financing Administration (HCFA)). As an example, in reviewing a hospital JCAHCO looks at a long list of structural measures such as the physical plant of a hospital and medical staff organization. The relationship, however, between some of these factors and health outcomes seems tenuous at best.[5]

Process is an important component of quality assessment because it focuses directly on the uncertainty in the efficacy of treatment. Given this

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[3] Donabedian, Avedis, "The Quality of Care: How Can It Be Assessed?" *Journal of the American Medical Association*, Vol 260, No. 12 (Sept. 23/30, 1988) pp: 1743-1748

[4] Wyszewianski, Leon, "Quality of Care: Past Achievements and Future Challenges" *Inquiry*, Vol. 25, No. 1 (Spring, 1988) pp:13-24

[5] JACHCO is moving toward adopting outcome measures of quality in addition to their structural measures. See O'Leary, Dennis, "The Joint Commission Looks to the Future" *Journal of the American Medical Association*, Vol. 258 (Aug. 21, 1987) pp:951-52

uncertainty, the logic of medical decision making is an important determinant of quality and cost effectiveness. Process measures are used by Peer Review Organizations (PROs) in reviewing the quality of care received by Medicare recipients and by organizations that perform utilization review. Generally examining the process of care involves assembling a panel of physicians who review medical records to determine the appropriateness of the care received. A number of studies employing this method have indicated that a significant proportion of the treatment provided to patients is inappropriate.[6]

As with structural measures of quality of care the relationship between process and outcomes is not well established. The information needed to determine the effect of process on outcomes is not yet available. Researchers examining the quality of medical evidence argue that, ". . .for at least some important practices, the existing evidence is of such poor quality that it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes which would have occurred with other options."[7]

One list of outcome measures could be described as "'the five Ds': death, disease, disability, discomfort, and dissatisfaction."[8] Outcome measures have intuitive appeal in that they can be relatively inexpensive to collect and appear to be easy to interpret. For example, HCFA has begun a program which releases hospital mortality rates in an effort to provide consumers with information on hospital quality. Hospitals indignantly, and correctly, pointed out that the problem with simple outcomes measures is that good quality care may not prevent a poor outcome and that providers treating sicker patients are more likely to have bad outcomes regardless of the quality of care they provide.

Simple outcome measures must be adjusted to account for factors other than the quality of care which might affect outcomes. These factors include the types of cases a provider treats (casemix), the severity of illness, and patient characteristics. A number of systems have been developed to measure case mix and severity. Diagnosis Related Groups (DRGs) classify inpatient admissions by diagnosis. They can be used to determine a hospital's casemix and are used by Medicare to reimburse hospitals. There are a number of systems such as APACHE and the Medical Illness Severity Grouping System (MEDISGRPS) which use physiological indicators to measure a patient's risk of dying to determine the severity of the patient's condition.

These and other similar systems have been used by providers and insurers to evaluate the quality and cost effectiveness of care. For example, a hospital can assign a severity measure to each patient within a DRG. Then the hospital can evaluate each physician's outcomes, using mortality or morbidity rates (such as length of hospital stay). Within each DRG the physician with the most severely ill patients should have the highest rates of bad outcomes and the highest costs. The accuracy of this style of quality evaluation depends upon the degree to which the severity and casemix measures capture the effects of factors other than quality on outcomes.

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[6]See for example, "Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services?" *Journal of the American Medical Association*, Vol. 258, No. 18 (Nov. 13, 1987) pp: 2533-37

[7]Eddy, David M., and John Billings, "The Quality of Medical Evidence: Implications for Quality of Care," *Health Affairs*, Vol 7, No. 1 (Spring, 1988) pp. 19-32

[8] Lohr, Kathleen N., "Outcome Measurement: Concepts and Questions" *Inquiry*, Vol. 25, Np. 1 (Spring, 1988) pp: 37-50

Patient satisfaction is an outcome measure that is relatively easy to collect. There have been a number of studies attempting to assess patient satisfaction and its relationship to the structure and process of care. In reviewing this literature Cleary and McNeil note that, "The most consistent finding in the satisfaction literature is that characteristics of the provider or the organization that make care more 'personal' are associated with higher levels of satisfaction."[9]

Satisfaction of course, is subjective. Attributes of care which some patients find satisfactory others may find unacceptable. The HMO industry regularly reports survey results which indicate that their enrollees are very satisfied with the care they receive. However, at least two studies have found high levels of dissatisfaction among HMO enrollees who were assigned, but did not chose, that style of care.[10]

The above discussion indicates that there is no single measure that adequately captures all the dimensions of quality of care. The definition of quality is at least in part subjective, but even the measurement of the characteristics of care over which individuals might disagree is incomplete. Moreover, the information necessary to determine if a limited set of easily observable characteristics, such as mortality rates, nurse to bed ratio, or board certification, could serve as indicators of quality is not yet available. The result is that it is unclear what exactly our health care dollar is purchasing.

Policy Implications

There are underlying causes for health care cost inflation other than market failure.[11] A growing, and aging, population and advances in health care technology increases the demand for health care services. The increased demand drives up costs as the health care industry competes with other sectors for resources. As a matter of public policy these increasing costs would not be troublesome if more health care were actually being provided. One definition of economic growth is more people purchasing more products.

The problem is that the market for health care services fails. The risks from the uncertainty in the efficacy of treatment have largely not been born by either providers or patients. There is not a market mechanism which evaluates the benefits of new, or existing, treatments against their costs. Instead, competition among providers encourages the adoption of new practices in order to offer a wider range of potential services. Providers who offer cost effective practice are not rewarded by the health care market in the absence of information justifying that style of practice. In most other markets price and quality rise together. Patients lacking any other information on quality may see no reason to move to a less expensive provider.

The market is unable to produce the amount of quality assessment necessary to ensure the provision of cost effective care. Cost management requires that quality assessment methodologies be developed and widely

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9 Cleary, Paul D. and Barbara J. McNeil, "Patient Satisfaction as an Indicator if Quality Care" *Inquiry*, Vol. 25, No. 1 (Spring, 1988) pp:25-36

10 See for example Welch, W.P., and Richard G. Frank, "The predictors of HMO Enrollee Populations: Results for a National Sample," *Inquiry*, Vol.23 No. 1 pp: 16-22 (Spring, 1986) and Garfinkel, S.A., W.E. Schlenger, K.R. McLerory, F.A. Bryan. B.J.B. York, G.H. Dunteman, and A.S. Friedlob, " Choices of Payment Plan in the Medicare Capitation Demonstration," *Medical Care*, 24 (7) pp:628-640, (July, 1986)

11 See Ginzberg, Eli, "A Hard Look At Cost Containment," *New England Journal of Medicine*, Vol. 316, No. 18 (April 30, 1987)

disseminated. Private firms have little incentive to expend the resources to develop quality assessment methodologies if other organizations can freely make use of those methodologies. However, to establish their credibility with providers and patients quality assessment firms must reveal their methodologies. Facing this paradox many third party utilization review firms will under supply quality assessment even in the presence of heightened demand for it.

The challenge for public policy is to promote both the research necessary to evaluate the quality of care and the incentives for providers to adopt cost effective practices. The cost management initiatives that have been implemented provide incentives to purchase and provide cost effective care but do not affect the majority of insured persons. More importantly the market cannot provide cost effective care until it can be determined what care is cost effective and what exactly the tradeoffs are between cost and quality. H.R. 1692, The Medical care Quality Research and Improvement Act of 1989 may provide the necessary first step in constructing an efficient health care delivery system.

University of Pittsburgh
GRADUATE SCHOOL OF PUBLIC HEALTH
Department of Epidemiology

May 22, 1989

The Honorable Fortney H. (Pete) Stark
Chairperson, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Representative Stark,

I recently heard of House Bill HR1692 to amend the Title XI of the Social Security Act to provide funding for research and education into the outcome, effectiveness, and appropriateness of medical treatments under the Medicare and other programs. The Bill is an important step in evaluating the quality and quantity of health care. Unfortunately, however, it has very serious flaws which will most certainly reduce or eliminate any benefits from the proposed legislation.

I spent a year with the House Select Committee on Aging, Health and Long Term Care Subcommittee chaired by Representative Claude Pepper about 5 years ago. The Committee held a hearing on Health Care Technology Assessment and made recommendations very similar to those in the proposed legislation. The key difference was the emphasis on scientific evaluation of the evidence.

Medical care costs and services are uncontrollable for the following relatively simple reasons:

1. The supply of disease in a population is probably infinite. We can generate a whole variety of new diseases and needs for treatments at almost a moments' notice. You can reduce the number of bypass surgical procedures and, I can assure you, within a relatively short time another new procedure would appear on the horizon to fill its void.

2. The costs and utilization of the services are therefore, determined by the resources to detect and treat diseases and the willingness of individuals to have their diseases detected and treated.

The only way that health care costs can be substantially reduced and services modified, is by influencing these two factors. This can be done either by rationing arbitrarily the availability of services, i.e., closing hospitals, reducing the payment to physicians or requiring long waiting times prior to having procedures performed, or by having a scientific evaluation of medical and surgical procedures prior to their widespread implementation into the community and restricting health services to only those procedures which are most effective. The second approach may result in a reduction of morbidity and mortality in the community and the first, generally increase complaints and has an adverse effect on the health of the community.

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The studies described in the press release "background" all relate to this very simple concept. It is not surprising that there are substantial variations in health services across the United States as well as between the United States and other countries. This has been known for many years. Health care costs and the quality of health care can only be modified by evaluating the scientific rationale through good clinical trials in humans before the particular treatments become widely available in the community, and (2) by controlling the uses of the various treatments and technology based on the scientific evidence by the payers, such as Medicare or other insurers. This approach is both scientifically sound and also is the most ethical method available.

Unfortunately, the Medicare program has failed to adhere to these guidelines and the result has been ever-increasing costs of the Medicare program. A good example of what happens is the decrease in length of hospitalization and utilization through DRG's and the consequent tremendous increase in health care costs in Part B. This again, is just an example of the fact that the supply of disease in the community is infinite and will shift from place to place as needed.

The Bill, as proposed, perpetuates the mistaken belief that one can judge the quality and quantity of medical care by reviewing databases. This approach is both unethical and scientifically unsound.

A recent article in the New England Journal of Medicine demonstrates these two points (Roos and Wennberg reported that men who had transurethral prostate operations had about a 50% higher mortality than open prostate operations, at 5 years the mortality was 35% from transurethral versus 25% from open prostatectomy. They could not explain these results from their objective databases. 95% of Medicare paid prostate operations are transurethral (Roos, N Engl J Med, April 27, 1989). There were 318,000 prostate operations over age 65 in 1987 in the United States, and since 1980 there have been a total of probably 3,000,000. The difference between 35% and 25% mortality at five years (10%) is about 300,000 lives. There has not been a clinical trial to evaluate whether open prostatectomy results in better survival than transurethral. Wennberg notes that, "We therefore recommend a prospective clnical study. Although the decline in the use of the open prostatectomy makes it difficult to conduct such a trial in most practice settings, the open operation remains the procedure preferred by some surgeons for the resection of larger glands. In Israel, approximately half the prostate operations are performed with the open approach. We hope that those who still advocate open prostatectomy can be stimulated to participate in a prospective trial." Wennberg is one of the leaders in the use of these objective databases, but even he recognizes their substantial weakness and the primacy of clinical trials.

Is it ethical to allow a procedure such as transurethral prostatectomy to be used for so many years and paid for my Medicare without any solid scientific evaluation as compared to open prostatectomy and then 10-20 years later, find out that maybe 200,000 - 300,000 excess deaths may have occurred. I do not believe that this should be the primary function of Medicare or the Medicaid databases.

There are three components to evaluation which have been noted since a classical paper by Hutchinson from Harvard in the early 1960's. These are: clinical trials to evaluate the scientific efficacy of the procedure, program evaluations to determine if the procedures are being used effectively in the community, and program reviews to follow-up and make sure that the procedures have been implemented. Unfortunately, the Bill focuses on these latter two points and not on the primacy of clinical trials, and therefore, has a substantial and very serious weakness. The Bill must expand the support of clinical trials and make this a top priority. Failure to do so will result in the loss of an excellent opportunity to improve the quality of medical care, and I believe, reduce the costs. Physicians cannot sit around the table, look at a dataset and decide what is and what is not good medical care. This is about as scientific as a group of elders sitting around a table and deciding that the earth is flat until proven that it was round.

The causes for variations in medical care utilization are so obvious that spending millions of dollars on more studies will be of relatively little value, and quite unfortunate. Surgeons are trained to do surgery and to earn a living. Fortunately or unfortunately, there are enough gallstones, hernias, nevus, occluded coronary and cerebral arteries, osteoarthritic knees enlarged uteri, and assorted polyps to keep them busy for many, many years. This is certainly not prejudicial against surgeons, but just to recognize what they are trained to do and that most of them do this with a high degree of quality. The major concern is to evaluate the scientific basis for new treatments, whether medical or surgical, and then to support those procedures which are effective as opposed to those that are ineffective. This must be done early before the procedures are widely disseminated in the community, and can only be done by carefully designed clinical trials. As you may know, very recently, a trial done by the National Heart, Lung and Blood Institute demonstrated that two widely used drugs for the treatment of cardiac arrhythmias, treatments paid for through the Medicare Program are toxic and result in excess deaths. If that trial had not been done, these two drugs would have continued to be used in the community and certainly would have resulted in a substantially increased mortality. There is almost no likelihood that the excess mortality associated with these drugs would have been clearly identified from databases, and certainly the use of these drugs had been widely supported by well-trained and well-meaning, highly qualified cardiologists in the United States.

I am enclosing a paper that I previously wrote that pretty well describes the state of affairs. I hope that the Committee will give very serious consideration to modifying the Bill so that the primacy of clinical trials and the need for the Health Care Finance Administration to substantially support the funding of these important clinical trials becomes a major priority of this legislation. Thank you very much.

Sincerely yours,

Lewis H. Kuller, M.D., Dr.P.H.
Professor and Chairperson

LHK/dm

American Journal of Epidemiology
Vol. 127, No. 1
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Reviews and Commentary

EPIDEMIOLOGY AND HEALTH POLICY[1]

LEWIS H. KULLER

Health policy analysis, like risk assessment, has become part of the popular public health mystique. There are probably many definitions of health policy. A simple one for the purposes of this paper is that health policy is the systematic approach to the evaluation and management of the quality and quantity of health care, including both prevention and health services. The quality of health care is usually measured as the structure, process, or outcome, and quantity is related to utilization and costs of services. The further introduction of epidemiologic methods into health policy analysis will reduce costs and improve the quality of health care.

Epidemiologists have considerable difficulty in dealing with health policy issues, especially health economics. The criteria for good epidemiologic studies are 1) a proper numerator and denominator, 2) the quality of the data collection, and 3) careful interpretation of the results, which often requires additional studies and many years of investigation. Epidemiologists are rarely satisfied with a single point estimate, but rather require multiple studies and careful analysis in order to estimate the impact of confounding and bias and to measure the confidence intervals around the point estimate. Health policy often depends on quick decisions, numerators without denominators, and the use of available data often collected for other reasons, rather than on unique, independently collected data. Size, recency of data sets, and applicability to the issues at hand are often considered to be more important than the quality of the data.

It is important to separate the effects of epidemiologic research on health policy, such as the introduction of new successful vaccines, from the use of epidemiologic methods to plan and implement national health policy. In a recent textbook, *Epidemiology and Health Policy*, Ibrahim (1) focused on epidemiologic methods as applied to the evaluation of health services and specific preventive medicine and clinical disease issues such as coronary heart disease, hypertension, maternal care during pregnancy, and infant care. However, the application of epidemiologic methods to the broad issues of health policy was not a primary focus. Holland and Wainwright noted that "the major contribution that epidemiology makes to the development of health services and improvement of health is no longer the subject for heated debate" (2, p. 211). They provide specific examples of these contributions, e.g., in finding the evidence of the relation of cigarette smoking to lung cancer and in child nutrition and air pollution control. Their emphasis, however, is on the value of epidemiologic studies and not on the implementation of the results of these studies to specific health policies. Other authors (e.g., Terris (3)) have also described the substantial successes of epidemiologic studies in determining both the risks of disease and methods of control. However, none of these reviews have gone on to the next step of evaluating the implementation of epidemiologic studies to the overall health policy of a com-

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This paper is based on a presentation given by Dr. Lewis H. Kuller as part of a symposium honoring Dr. George W. Comstock, at The Johns Hopkins University, Baltimore, MD, January 9, 1985.

munity or a country such as the United States.

The definition of important health policy issues depends on the interest of the users. Legislators at the federal government level in Washington, DC, and probably also at the state government level are primarily concerned with health care costs, especially as related to federal and state payments (table 1). The increased appropriations in both the federal Medicare program and the federal and state Medicaid programs have been of primary importance in bringing about major changes in health policy in recent years (4). The costs of part B of the Medicare program are especially critical since these costs are heavily funded from general tax revenues, as compared with part A of the Medicare program, which is paid for by the Medicare Trust Fund. The threat of insolvency of the trust fund has been used as an effective tool to manipulate health policy. It is important to recognize that the quality of health care, especially outcome measures, has been of relatively little importance in legislative health policy. That situation may, however, be changing. For example, there appears to be an increasing interest in the outcome of health care as measured by hospital case fatality rates (5). Fear that cutbacks in health care payments may adversely affect outcome has generated at least this much interest in the quality as well as the quantity of health care (6). Furthermore, the equitable distribution of health services, particularly for poor and elderly persons, is certainly becoming a more important component of legislative health policy (7).

Health policy professionals who make their living analyzing trends and recommending new policy, especially as related to health services, also have a primary interest in the quantity and costs of health care (table 1). The health policy analyst generally agrees that health services have some relation to outcome. A leading health policy analyst recently noted, "The one aspect of Medicare on which there was strong consensus is that the program has benefited the nation's elderly. Beginning in 1968 after a 12-year period of almost no change, a rapid decline in mortality among the elderly occurred and has continued at rates that exceed that of other western countries" (8, p. 1196). There is clearly a striking "relation" between changes in health care expenditures and the decline in death rates

TABLE 1

Major health policy considerations

Politicians
The cost of medical care is too high.
The Medicare program is going bankrupt.
Doctors charge too much and there are too many of them.
There are too many hospital beds and hospitals.
Professionals
There is an overutilization of health services, especially in certain areas of the country.
There is an increase in the "intensity" of health services, i.e., technology, which results in increased costs.
The impact of the improved health care services over time has resulted in decreased death rates and increased life expectancy.
The increase in the old-old, i.e., persons aged 80+ years, will have serious impact on health services.
Variations in health care delivery will reduce health costs.
Public health advocates
The health of the American public has improved substantially as demonstrated by declining death rates.
Major public health programs have been successful in reducing key risk factors such as cigarette smoking, control of hypertension, and dietary changes.
Accessibility and distribution of health care have improved over time.
Environment monitoring and control have helped decrease morbidity and mortality.
A planned strategy to reduce certain risk factors and health hazards will reduce morbidity and mortality.
Prevention is the cornerstone of effective health policy.
Consumers
Personal out-of-pocket health costs are too high.
Long-term care services, e.g., nursing home care, are not provided.
Quality medical care is often not provided.
There are substantial risks to the public from environmental hazards such as radiation, chemicals, food additives, and occupational exposures.
The medical establishment suppresses new "therapies."

(figure 1) (4, 9). Epidemiologists would be suspicious of making a generalization about this relation, since in fact the death rates have declined by about the same degree in the younger age groups, who are not part of the Medicare population, as in the older age groups and have been declining at about the same rate in many other countries (10). The common features in most of these countries have been increases in per capita health care costs (11) and, probably most important, improvements in the standard of living and level of completed years of education. It is also important to remember that measures of morbidity and disability have changed little over time as compared with mortality. Thus, 12.1 per cent of the population in 1976 and 11.8 per cent in 1981 reported their health as fair or poor (4).

Some people would argue that health care delivery and the amount of health services provided have relatively little to do with health outcomes. In that case, health services can be treated like any other service industry and modified by similar marketplace forces, such as competition and federal and state controls, with little concern about health outcome.

Hospital costs now account for about 69 per cent of Medicare benefit payments, an estimated 46.1 billion dollars in 1984 as compared with 3.1 billion dollars in 1967 (4). The increase in costs above that due to inflation has not resulted primarily from the greater frequency of hospitalization or aging of the Medicare population, but rather from the greater intensity of care within the hospital, such as more diagnostic and treatment procedures, including a greater number of surgical procedures (12). This is often referred to as the intensity factor and may account for up to 25 per cent of the increased cost over time.

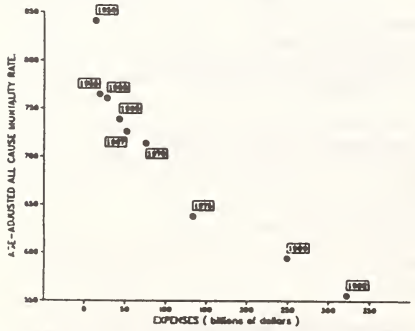

FIGURE 1. The relation between national health expenditures and age-adjusted all-cause mortality rates, United States, 1950–1982.

Proper and essential evaluation of health care technology—particularly as to diagnostic instrumentation and surgical procedures—is rarely made with regard to objective measures of outcome as opposed to process and safety. The primary emphasis has been on the process. The prevailing beliefs have been that if the technology is being applied to measure disease it must be useful as long as it does not injure the patient and, secondarily, that more health care is always better than less health care. The combined overutilization of services and greater intensity of care should be amenable to modifications by changes in the health care delivery system.

The increased population of persons aged 80+ years (13), due both to the declining death rate and to other demographic changes in the United States, presents yet another important policy issue. The number of such persons will probably double in the next 10–15 years. Their needs for long-term care services and institutionalization, nursing homes, and other similar types of facilities are not adequately met by the Medicare program, which does not include any substantial funding for long-term care (14). This increasingly large elderly population is a particular challenge to the epidemiologist: first, in terms of understanding the determinants of disability and loss of independence, and, second, because of the increasing prevalence of specific diseases such as Alzheimer's disease, osteoporosis, and osteoarthritis.

The public health advocate looks at health policy somewhat differently (table 1). The issues primarily relate to health outcomes rather than to the quantity of

care and cost. The impressive declines in death rates in the United States can be attributed to disease prevention. Death rates for most diseases except lung cancer and chronic pulmonary disease are declining in the United States (9). The decline has occurred in all race, sex, and age groups. As noted, the decline is also occurring in many other countries. A national health policy to further reduce morbidity and mortality has been established and has been published as *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention* (15). A blueprint for carrying out these actions is described in several documents published by the US Public Health Service (16).

Although preventive medicine is considered a high priority at least for the public health advocate, the actual financial commitment in relation to total health care costs is minimal. In 1980, of 249 billion dollars spent for health purposes, only 3 per cent (7 billion dollars) was used for organized government public health activities. Of this 7 billion dollars, 1.3 billion dollars was used for federal public health activities including health planning, disease prevention and control, and consumer and occupational safety and health, and 5.7 billion dollars was used for state health department activities (4). Major federal programs such as Medicare or Medicaid specifically exclude most preventive actions. Medicare, for example, covers the cost of only two specific preventive measures—pneumococcal and hepatitis B vaccines. Medicaid includes an early periodic screening and detection program for children, but there is little emphasis on preventive programs for the rest of the high-risk population. An ever-increasing percentage of Medicaid funds is being used for the care of the institutionalized elderly.

Two aspects of public health policy that are particularly worrisome are the separation of preventive medicine from the rest of health care, and the belief that preventive medicine will be a panacea to stem much of the rising health care costs (17).

There is a concern that prevention is being proposed as a relatively cheap substitute for a national health insurance system that would provide quality and access to care for everyone. Roemer stated that "raising the banner of prevention, therefore, coincided very nicely with retreat from NHI [National Health Insurance]; presumably, it was both cheaper and better" (18, p. 244). A national health policy must combine both prevention and health services.

Finally, consumers of health services have a rather different view of health policy (6) (table 1). Their major concern is costs, especially out-of-pocket costs (19). It is important to recognize that Medicare alone covers only about two-thirds of health care costs for the elderly (table 2).

Consumers are often less concerned about being the "victims" of their life-style habits, such as smoking, drinking, and diet, than about the serious consequences of the environment on their health and their inability to receive the quality of medical care that would lead to either a cure or a substantial reduction in disability. Frustration with many of the failures of current medical therapies to cure all diseases often results

TABLE 2

Per capita out-of-pocket health care costs for persons aged 65+ years in 1977 and 1984, by type of service and percentage of total costs*

	Total cost	Out-of-pocket		Percentage distribution*			
		Cost	%	Insurance	Hospital	Physician	Nursing home
1977	$1,785	$522	29	6	7	17	41
1984	$4,202	$1,059	25	7	6	21	42

* Per cent of out-of-pocket costs, excluding per cent of other costs (19).

in the blind acceptance of unorthodox and widely advertised therapies that are tantamount to medical quackery. Recent Congressional hearings have documented that health quackery is a 10 billion dollar a year business (20). More funds are probably expended for the advertising of health quackery than for health education or most preventive programs.

One goal of the epidemiologist in health planning is to try to synthesize these varied health policy views. The key determinants of health policy can be classified into the classical triad of host, agent, and environment (table 3). Numerous other variables obviously contribute to the list, but, as will be shown below, almost all relevant interrelations between quality, quantity, and cost of health care, including preventive medicine, can be accounted for by these variables.

The first step is to define a series of testable hypotheses (table 4). The first hypothesis, i.e., that the amount of disease or pathology in a population is practically infinite, is critical since it probably undermines much economic theory related to health care. There are several examples to substantiate this hypothesis. For example, the prevalence of gallbladder disease identified at postmortem examination either as silent stones or prior cholecystectomy is exceedingly high. As many as one-third of all women over age 50 years have evidence of gallbladder disease, at least based on postmortem examination (21). There is clearly enough gallbladder disease to keep most surgeons in the United States busy for many years. The prevalence of surgical treatment of gallbladder disease varies substantially, both over time and by geographic area (22, 23). In fact, there is a severalfold variation in the frequency of cholecystectomy and other surgical procedures be-

TABLE 3

Epidemiology and health policy determinants of health care utilization and costs

Host	Agent	Environment
Age and race	Technology	Health resources
Sex	Disease	No. of physicians
Socioeconomic status	Symptomatology	No. of hospitals and beds per capita
	Health insurance	Other facilities
	Out-of-pocket costs	

TABLE 4

Epidemiologic basis of health policy: hypotheses to be tested

1) The amount of disease or pathology in a population is practically infinite.
2) The probability of detecting disease is finite and is a function of:
   The amount of disease or pathology.
   The probability of detecting disease which depends on technology and accessibility of the population (risks and costs).
3) The probability of treating disease is finite and depends on:
   Medical or surgical technology.
   Extent of symptomatology and disability (natural history).
   The available supply of health resources.
   The cost of treatment versus no treatment.
4) The costs of health care are a function of the probability of detecting and treating disease and can be diminished by:
   Decreasing the extent of disease detection.
   Reducing the types or amount of treatment.
   Reducing the unit cost per diagnosis or treatment.
5) Nonselective reduction in the extent of disease detection and reducing the types or amount of treatment will result in increased morbidity and mortality if medical care is related to outcome.
   The reduction in the unit cost per diagnosis or treatment will also have an adverse effect if costs are related primarily to quality and secondarily to outcome.
6) If the amount of disease in a population is infinite, then prevention of any single disease, e.g., specific cancer, tuberculosis, or measles, will not affect the cost or amount of disease in a population.
7) Prevention will:
   Reduce specific morbidity and mortality.
   Increase longevity by eliminating disease or delaying time from disease onset to morbidity and mortality.
   Reduce the costs of specific diseases and thus shift the distribution of health care costs.

tween areas of the United States and between the United States and other countries (22). There is no evidence that this variation is related to the prevalence of underlying disease which is primarily a function of sex, age, diet, and genetic factors, but rather is related to detection and indications for treatment. There is also little evidence, for example, that the frequency of gallbladder surgery is in any way related to either complications of gallbladder disease or cancer of the gallbladder.

Another example to substantiate this hypothesis is the surgical treatment of carotid artery stenosis, a relatively new phenomenon. The prevalence of undetected carotid artery stenosis, that is, an occlusion or stenosis of a carotid artery, is unknown but is clearly substantial. Probably about 20 per cent of older persons have carotid artery bruits that can be easily identified (24). We demonstrated that about 50 per cent of persons over age 60 years who had systolic hypertension had flow-significant carotid artery disease. New diagnostic methods such as B-mode ultrasound and Doppler flow measurements have made it possible to detect carotid artery stenosis noninvasively. In 1984, Dyken and Pokras (25) reported a substantial increase in the surgical treatment of carotid artery stenosis. For example, the number of procedures increased from 15,000 in 1971 to almost 82,000 in 1982 with a continued approximate 3 per cent case fatality rate. There is no apparent increase in the prevalence of underlying disease, but rather in increased detection and treatment. Thus, the absolute number of deaths after the procedure is also increasing. Furthermore, about half of the procedures in a community are apparently done for asymptomatic disease (26). To my knowledge, no clinical trials have demonstrated that such surgical procedures are beneficial to the patient in reducing the risk of stroke or cardiovascular mortality.

Another reason for the infinite supply of disease in a population is the continued identification of new diseases, either such real diseases as acquired immune deficiency syndrome or redefined symptomatology such as the premenstrual syndrome (27, 28), which apparently affects 25 million women in the United States. Treatment and diagnostic centers for premenstrual syndrome are now expanding across the United States. This observation is not to denigrate the symptoms related to menstruation, but rather to point out the ingenuity of the medical profession in identifying diseases requiring specific treatment. Todd noted, "Over the years specialists have been responsible for a long succession of bogus diagnoses—neuritis, fibrositis, sacroiliac strain, lumbosacral back strain, intestinal autointoxication, retroverted uterus (as a cause of backache), primary cardiac overstrain, chronic appendicitis, visceroptosis, chronic cholecystitis, hyperchlorhydria, gastritis, and so on" (29, p. 1089).

The acceptance of the hypothesis of an infinite supply of disease means that primary prevention is unlikely to substantially decrease utilization of services or health care costs, but rather to shift services and costs from one medical problem to the next.

The extent of treatment of disease in a population is finite (table 4) and is influenced more by detection than by the extent of underlying pathology. The extensive variation in treatment of specific diseases by area has been carefully documented (22). The key determinants appear to be the supply of physicians and hospital beds and the amount and type of insurance. Similarly, the frequency of medical diagnostic procedures is also both increasing and remarkably variable from region to region (30). For example, there has been a tremendous increase in the frequency of coronary angioplasty, a relatively new procedure that can be done by a cardiologist. Interestingly, as the frequency of this procedure has risen, there has also been a continued increase in coronary bypass surgery, rather than the decrease that might have been anticipated to follow the introduction of a competing procedure.

As the urgency and critical nature of the procedure increase in importance, the variation across areas declines. The increasing availability of health insurance in the population, especially through the federal Medicare programs, has substantially reduced the difference in utilization of services by socioeconomic status (31), particularly the prevalence of specific surgical procedures. Thus, based on our model of host, agent, and environment, the last factor—the number of doctors, surgeons, and hospitals—may be the most critical variable determining the prevalence of medical care in combination with certain agent factors such as technology and health insurance.

The quantity and cost of health care can be reduced by modifying either detection or treatment, or the cost per unit of treatment or detection (32). Increasingly, the government and other health care providers have attempted to create barriers to the utilization of services by making the patient pay for some of the costs of diagnostic procedures and medical care or by restricting the availability of technology through such activities as second opinions prior to surgery or controlling the supply of technology by requiring some type of certification prior to purchase or use.

It is clear that health maintenance organizations (33) and insurance policies with high deductibles, so called catastrophic plans, substantially decrease the extent and cost per capita of treatment, as shown in the Rand Health Insurance Experiment (32). The government has further attempted to reduce the per unit cost of a procedure or technology through such actions as the Tax Equity and Fiscal Responsibilities Act (TEFRA) Amendments of 1982, which fixed the increase in overall Medicare health care costs, the Diagnosis Related Group prospective payment systems, or Preferred Provider Organizations (34). These approaches attempt to reduce the unit cost per diagnosis or treatment.

It is also important to recognize that influencing the provider, that is, the physician, through professional health education is probably going to be much less successful. Levinsky noted that "physicians are obligated to do all that they can for their patients without regard to any costs to society" (35, p. 1573–4). "A similar danger lurks if physicians attempt to conserve resources by using probabilities of success or failure to make decisions about the care of individual patients. Estimates of the probable outcome of clinical condition in a given patient are almost invariably based on 'soft data': uncontrolled studies, reports of cases of dubious comparability, or the physician's anecdotal clinical experience—all further devalued by rapidly changing diagnostic and therapeutic techniques. The standard errors of such estimates are undefined but undoubtedly large" (35, p. 1574). The cost of health care will probably not be determined by the extent of underlying disease in the population or changes in physicians' behaviors through medical education (36).

Up to this point, the question of the quality of health care and patient outcome has not been extensively considered. If detection and treatment of disease have an overall health benefit, then reduction in either detection or treatment should result in an adverse outcome measured as increased morbidity or mortality or at least a reduced quality of life (table 4). Thus, nonselective rationing of health care could be harmful to the health of the population (37, 38).

Lohr and Brook (39) have stated that the relation between the amount of health care resources and quality measured as outcome may not be linear beyond a certain point. Defining the particular point of diminishing returns is difficult and would require careful clinical trials and evaluation. Similarly, a decrease in the unit cost per diagnosis or treatment could have adverse effects if there were a linear negative relation between costs and quality.

Bunker et al. (40) and Wennberg (37) demonstrated striking evidence for a negative relation between the frequency with which specific surgical procedures are done

in a hospital and the case fatality percentage. The fact that increased experience appears to lead to improved quality of care may account for some of the differences in patient outcome by surgeon in a recent study of all carotid endarterectomies in a major US city (41).

Restrictions on the use of health care providers based on cost rather than quality as is now done in several of the state Medicaid programs are examples of attempts to reduce unit cost per diagnosis and treatment (42, 43). Such approaches could also result in the reduction in the quality of care. However, whether such restrictions adversely affect the health of the consumers has not been adequately tested. Several recent reports have suggested that they do (42, 43). The worst aspect of such changes in Medicaid programs is that they represent uncontrolled trials of possible changes in quality of health with little effort to measure outcome other than cost.

The amount of available health resources is clearly limited. The arbitrary limitation of resources may be related to adverse health outcomes and increased morbidity and mortality. Inequities in the distribution of health care could also be hazardous by shifting limited resources from more effective to less effective care, for example, by providing high-technology procedures for only a few seriously ill patients or by denying preventive health care. It is also important to recognize that some of the costs of health care might be more efficiently used in other areas, such as education, housing, or the creation of new jobs. A recent conference in Toronto, Canada, "Beyond Health Care," noted that "benefits to health from actions taken outside the immediate health sector can far outweigh those secured within it" (44, p. 1387).

A systematic approach to health services and prevention clearly offers the best opportunity to conserve resources and improve the quality and outcome of health care. The best approach is by a classification system based on our knowledge about the prevention and treatment of specific diseases. The staging evolves from stage I, in which both the specific etiology or cause of a disease and its treatment are unknown, to stage VII, which includes diseases controlled primarily by environmental management.

In stage I diseases (table 5), the specific etiology and treatment are unknown. Many chronic diseases are in this category. The cost of care is often high due to multiple diagnostic tests, nonspecific treatment to modify pain and disability, and the high costs of intensive care associated with fatal diseases. For example, between 1974 and 1977, 2.6 per cent of the Medicare population had five or more hospitalizations and accounted for 20.3 per cent of costs (45). Furthermore, 5.9 per cent of the Medicare population dies each year and accounts for almost 28 per cent of costs. Changes in treatment of disease in this category by modifications of the health care delivery systems, such as Health Maintenance Organizations, may provide a substantial opportunity to reduce cost with minimal impact on outcome or quality of life. The primary emphasis for the epidemiologist is on descriptive epidemiology, including a better understanding of the natural history of disease and the search for major risk factors. Experimental studies are primarily limited to the evaluation of health care delivery systems and cost containment.

In stage II diseases (table 5), the etiology is still poorly defined, and the treatment is primarily surgical. Secondary prevention by early detection and nonspecific medical therapy often complement surgical therapy. There may be slight decreases in disease-specific mortality rates. The epidemiologist is again primarily concerned with the evaluation of risk factors, analytic epidemiology, and early detection and treatment of disease. Costs remain high because of the use of high technology for diagnosis and treatment, numerous recurrences, and the high case fatality rate. Variations in case fatality could be a function of the quality of care. The quantity and unit cost of delivery of health care in stages I and II most

TABLE 5

Evolution of health care for a specific disease

Stage	Example	Treatment and prevention	Implications and health services	Role of epidemiology
I. Specific etiology and treatment unknown	Many psychiatric diseases Many cancers Chronic neurologic disease Rheumatoid arthritis	Nonspecific Drug therapy for reduction of disability, pain, etc.	High frequency of diagnostic tests Long-term recurrent episodes may result in high costs, especially for fatal disease	Descriptive and analytic epidemiology Risk factors Evaluation of health care
II. Etiology unknown; disease better defined	Gallbladder disease Osteoporosis Peripheral vascular disease Breast and colon cancers	Surgical therapy and nonspecific medical therapy Screening and early detection	As in stage I Some decrease in mortality and case fatality possible	Analytic epidemiology Evaluation of early detection and treatment
III. Etiology and treatment better defined	Insulin-dependent diabetes Coronary artery disease (1984) Leukemia and lymphoma Peptic ulcer Stroke	Specific medical therapy begins to replace or complement usual surgical therapy Identification of high-risk persons	Decreased length of hospitalization Frequent recurrences and high costs of technology Some reduction in mortality Lower case fatality per cent	Analytic epidemiology Evaluation of early detection and treatment Clinical trials
IV. Etiology and treatment better defined	Cervical cancer Pneumonia and influenza Hypertension	Screening and early detection, medical therapy oriented to prevention Specific surgical treatment of early disease	Decreased morbidity and mortality Costs depend on balance of decreased disease versus increased "at risk" and use of technology	Analytic epidemiology Evaluation of early detection Clinical trials of treatment Community public health programs

V. Etiology well-defined	Lung cancer Chronic obstructive pulmonary disease Non-insulin-dependent diabetes Cirrhosis of the liver Homicide Accidents	Prevention available, not implemented Relatively unsuccessful prevention efforts Nonspecific medical and surgical therapy	Disease often treated as in stage I Costly High technology, often sociopolitical and controversial Greatest opportunity for effective public health programs	Primary prevention Modification of risk factors Health education
VI. Etiology well-defined	Many infectious diseases Poliomyelitis Tuberculosis Smallpox Dental caries Nutritional deficiencies Scurvy Pellagra	Primary prevention Medical therapy only for a small subgroup at risk	Decreased morbidity and mortality Marked decrease in costs	Primary prevention program surveillance Public health education
VII. Environmental control of disease	Infectious diseases Typhoid Cholera Malaria Botulism Hepatitis Encephalitis Occupational diseases Environmental exposures Air and water pollution Toxic chemicals Ionizing radiation	None Environmental control	Disease absent or rare in population Often decreased morbidity and mortality and marked decrease in costs Inappropriate application of known prevention may lead to disease	Monitoring of environment Descriptive epidemiology of disease sentinels (biologic markers)

likely account for the substantial variations in health care costs among areas and probably have less effect on differences in mortality rates. Efficient delivery of health care offers great potential for cost reduction with minimal effects on quality, morbidity, and mortality.

Stage III represents the beginning of the preeminence of specific medical therapy and better defined surgical care (table 5). Early detection and treatment are also better defined. Specific medical therapy begins to replace surgical treatment. For example, the introduction of the drug cimetidine in the treatment of peptic ulcer resulted in a substantial decrease in surgical therapy (46). In addition, early detection and treatment of diseases in this stage are now possible. Epidemiologists focus on refining the definition of risk factors and on clinical trials of specific treatments. Some reduction in both the case fatality and mortality rates is possible. Providing maximal health care, including prevention, to reduce mortality may be possible, but at considerable cost. Reduction of health care services may be associated with increased mortality rates because of higher case fatality. An interesting recent report noted that persons treated in a geriatric unit had a much better survival rate after hospitalization compared with those who had hospital care in a nongeriatric unit (47). Careful monitoring of the quality of care and outcome is extremely important.

Stage IV diseases (table 5) are generally better defined in terms of etiology and specific treatment. Both specific medical and surgical therapies are oriented toward prevention of complications. Early detection and treatment and secondary prevention are extremely important. Primary prevention is attempted and is successful in reducing morbidity and mortality. The prevention of rheumatic fever and rheumatic heart disease (48) and the detection and treatment of hypertension (49) to prevent complications are good examples. Specific disease costs may be substantially reduced, although screening, early detection, and treatment may increase costs. Decreased available health services may result in greater morbidity and mortality. The epidemiologist is primarily concerned with the identification of risk factors, such as the primary prevention of hypertension, and with clinical trials and the development of community prevention programs.

Stage V diseases (table 5) are of great public health concern. These are diseases in which the etiology and methods of prevention are well-defined, but implementation in the community is poor. Most of these diseases are caused by specific health behaviors such as cigarette smoking, alcohol consumption, diet, etc. There are certain important aspects of these diseases. Their morbidity and mortality vary substantially among communities (50–53), and along with certain of the diseases in stages III and IV, they account for the major racial and socioeconomic variations in mortality.

The most important determinant of the distribution of these diseases is education or other markers of social class. Tremendous differences in mortality by race and sex still persist within the community. For example, in Allegheny County, Pennsylvania, in 1979–1981, black men had seven times higher total mortality than did white women aged 25–34 years (table 6). Most of these differences are related to preventable diseases. Within the city of Pittsburgh, age-adjusted death rates for white men varied almost threefold by geographic area, with the variable of primary importance being social class. Further studies of areas with high and low death rates in Allegheny County, Pennsylvania, have clearly demonstrated that the major reasons for these

TABLE 6

Age-specific death rates per 10,000, by race and sex, Pittsburgh, PA, 1979–1981

Age (years)	Women		Men	
	White	Black	White	Black
25–34	6	14	16	43
35–44	16	35	37	72
45–54	49	89	99	159

differences in rates are primarily health behaviors such as cigarette smoking, alcohol consumption, obesity, and the treatment of hypertension (table 7). Improved education and economic conditions continue to represent the most important public health effort.

There are important implications for health economics that are also related to diseases in stage V. First, the treatment of these basically preventable diseases is extremely difficult, and the outcome is less than satisfactory. For example, the treatment of lung cancer is not very effective and is costly. We might consider the cost of treating these diseases as unnecessary health care costs. Funds consumed in the treatment of these diseases will have little impact on outcome, while preventive efforts have great potential for reducing specific costs and decreasing morbidity and mortality rates.

Diseases listed in stages VI and VII (table 5) are the primary concerns of traditional public health practice. The great success in controlling most of these diseases by primary prevention such as immunization or environmental control should be an impetus for similar successes for prevention of other diseases, especially those in stage IV. The cost of treating these diseases has been substantially reduced, even with the inclusion of the cost of immunization and surveillance. The control of primary nutritional disorders such as pellagra, scurvy, and goiter also suggests that control of the modern disorders related to nutrition, such as non-insulin-dependent diabetes, hypertension, coronary artery disease, and some cancers, is also feasible (54, 55).

Stage VII diseases are principally controlled by environmental management. Many of the triumphs of preventive medicine have resulted from the introduction of environmental controls for these diseases. Nevertheless, with the burgeoning numbers and amounts of environmental contaminants, more remains to be done (56). These needs are illustrated by public concerns about toxic waste dumps and the paucity of peer-reviewed scientific papers that have attempted to measure the health risks associated with such exposures (57–60). Stage VII diseases still constitute a considerable public health problem and present epidemiologists with many opportunities for the kinds of research needed to make intelligent health policy decisions.

In summary, the important implications of this epidemiologic analysis of health policy are that prevention is probably the only effective method of reducing morbidity and mortality and that it will have only minimal effects on total health care costs. The control of health care costs will depend not on the reduction of the prevalence of pathol-

TABLE 7

Comparison of certain characteristics between two communities in Allegheny County, PA, higher and lower death rates, whites only, aged 25–64 years

	Death rates (%)			
	Men		Women	
	Low (n = 189)	High (n = 179)	Low (n = 306)	High (n = 243)
Divorced	5.8	2.2	5.9	6.2
13+ years education	20	69	14	57
History of diabetes	3.5	3.8	7.6	4.2
History of heart disease	8.7	5.9	6.1	2.9
Cigarette smoking	45	26	40	27
Alcohol consumption (5+ drinks/day)	16	2	0.8	0.0
Obese	19	10	19	8
History of hypertension	36	29	32	24
Blood pressure ≥90 mmHg	27	17	14	9

ogy in the population, but on the control of diagnostic technology, the extent of treatment, or the unit cost per treatment. Such changes are unlikely to occur by education of health care providers; they are more likely to come about by manipulation of the health care delivery system, by government control, or by some method of expanding competition. The epidemiologist has a major role to play in carefully monitoring both quality and quantity of health care, especially objective measures of health, such as changes in incidence, mortality, or extent of disability. Randomized clinical trials are particularly important. The epidemiologist must constantly press for quality data and adequate information for rational health policy. Without such epidemiologic input, too many health policy decisions will continue to be based on untested opinions and expert consensus rather than on the scientific bases of medical practice, including preventive medicine.

It is possible that indiscriminate reduction or attenuation of the increasing health care costs will adversely affect the quality of health care and objective measures of outcome such as morbidity and mortality. The accuracy and accessibility of our data collection system are as important now as they were 20 or 30 years ago. An adequate data base is essential to measure the changes in the quality of health care.

Finally, the most important determinants of the health status of a population are socioeconomic factors, especially education. The continued increase in the educational levels of the US population (61) probably guarantees a further decrease in death rates, especially among the elderly, short of any new major epidemics (figure 1). Mortality rates are higher among minorities and lower socioeconomic classes (62, 63). Much of the differential is due to preventable diseases. The critical challenge to public health policy is to narrow the socioeconomic gradient in morbidity and mortality and to encourage more positive health behaviors in the total population (64).

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Statement
for
The Subcommittee on Health
Committee on Ways and Means
United States House of Representatives

Regarding
HR-1692
The Medical Care Quality Research and Improvement Act

Prepared by

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The Board of Directors on behalf of the Society for Clinical Trials is concerned about the current language in the proposed legislation HR-1692 entitled "Medical Care Quality Research and Improvement Act of 1989". While the Society enthusiastically supports the evaluation of medical therapies, procedures, and devices for their appropriateness and cost effectiveness, the current language does not specifically mention the best method to perform this evaluation, namely the randomized control clinical trial.

During the past three decades, clinical scientists in a broad range of disciplines, including heart disease, cancer, eye disease, and, more recently, AIDS, have relied on the randomized control clinical trial as the best scientific method for evaluating new medical therapies. The fundamental principle is that two or more competing therapies are evaluated in an unbiased manner under the same conditions. The process of randomization eliminates selection bias. Selection bias results when, for example, clinicians have a preference for patients being placed on one therapy or another according to the patients assessed risk. Randomized control clinical trials have been used to evaluate surgical procedures such as coronary bypass surgery, devices such as laser treatment for diabetic retinopathy and insulin pumps for the diabetic, and drugs such as recent trials of aspirin for the primary prevention of heart attacks, the recent trial of anti-arrhythmia drugs for prevention of sudden death, and the role of complex combinations of drugs or biologics in the treatment of cancer. The success rate of the randomized control clinical trial for careful unbiased evaluation of new medical therapies during the past three decades is very impressive.

Alternative strategies often suggested, such as the use of existing data banks, data registries, or non-randomized control studies, are inherently vulnerable to biases of patient selection and changes over time in patient referral patterns, definitions of disease, or in the disease incidence itself. No statistical methodology can compensate for these design deficiencies. Thus, interpretation of analyses from such studies can be difficult to interpret and misleading. Often such analyses overestimate the degree of benefit if one exists. If the evaluations proposed in this legislation are conducted by these alternate methods, there is a high likelihood that little clarity or resolution of these important issues will be achieved without controversy and further study.

Since most alternative research strategies have serious deficiencies, clinical researchers and statisticians have relied on the randomized control clinical trial as the standard by which critical evaluations of new therapies are conducted.

Recommendation

The Society urges that the proposed legislation include language to specify the randomized control clinical trial as the experimental method of choice wherever possible to implement.

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